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# Building a Better Laboratory: The Federal Role in Promoting Health System Experimentation

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# Building a Better Laboratory: The Federal Role in Promoting Health System Experimentation

Kristin Madison\*

## Abstract

*While expanding federal involvement in the health care system, the Patient Protection and Affordable Care Act (ACA) preserves states' roles as policy laboratories and private providers' roles as health care delivery laboratories. State-based and provider-based laboratories suffer from many shortcomings, however, as mechanisms to develop, evaluate, and facilitate diffusion of reforms within the health system. This Article argues that the federal government can take steps to address these shortcomings. It first briefly reviews ACA provisions that promote policy and delivery experimentation. It then suggests that by tying funding to policy outcomes, making use of regulatory variation and regulatory menus, and conditioning waivers on systematic evaluation, the federal government could further improve the performance of the nation as a laboratory.*

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## I. INTRODUCTION

The Patient Protection and Affordable Care Act (ACA)<sup>1</sup> has the potential to completely transform the American health care system. Easily the most significant piece of federal health care-related legislation since the adoption of the Medicare and Medicaid programs, it will expand the availability of health insurance and change the way that individual and small group insurance markets work. It will also accelerate health care delivery reforms. Whether the ACA achieves its full potential as a transformative force, however, remains to be seen. It may spur more evolution than revolution. Its success and speed in achieving policy goals such as expanding access, limiting costs, and improving quality will depend on its ability to foster innovation in health care coverage, finance, delivery, and regulation.

The ACA provides an opportunity to study innovation in a context in which federal, state, and private actors all play important roles in effecting change. Health care providers continually seek new ways to improve patient care. State governments frequently try out new approaches to expanding health care access and regulating health care providers. At the same time, the federal government is increasingly taking responsibility for financing health care. With this increased responsibility has come an increased interest in pushing for changes in the health care system. The ACA proceeds even further in this direction. While preserving important roles for states in managing access to the health care system, the ACA relies heavily

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1. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

on federal reform as an engine for health system experimentation.

The term “health system experimentation” is intended to capture many distinct but interrelated concepts. By “health system,” I mean not just the health care delivery system, but also the regulatory framework that supports it and the policies that shape it. By “experimentation,” I mean not just the initial conception or implementation of a new approach to health care delivery or a novel regulation or policy, but also the longer-term processes of evaluating and promoting the diffusion of innovations.

The ACA innovates in many ways. Just by virtue of its status as a newly enacted federal statute, it necessarily engages in policy innovation of a sort: it imposes new mandates. It requires individuals to purchase health insurance or pay a penalty,<sup>2</sup> requires large employers to provide insurance or pay a tax,<sup>3</sup> and prohibits insurers from charging higher premiums or refusing to issue policies based on individuals’ health status.<sup>4</sup> At the same time, the ACA seeks to encourage further innovation in both policy and delivery through exceptions to its mandates.<sup>5</sup> It permits waivers, for example, for states that adopt alternative means of ensuring coverage for their residents.<sup>6</sup> It also provides for waivers of certain existing mandates, such as fraud and abuse laws that might otherwise impede the development of accountable care organizations (ACOs), which policymakers hope will improve the quality and efficiency of health care services.<sup>7</sup>

Perhaps the most obvious evidence of the ACA’s commitment to experimentation is its creation of demonstration projects and new institutions devoted to promoting innovation in health care policy and delivery. For example, the part of the legislation entitled “Encouraging Development of New Patient Care Models”<sup>8</sup> describes a variety of demonstration and pilot projects, such as a program under which payments to providers will be

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2. See Patient Protection and Affordable Care Act § 1501, 42 U.S.C. § 18091 (2012).

3. See Patient Protection and Affordable Care Act § 1513, 26 U.S.C. § 4980H (2012).

4. See Patient Protection and Affordable Care Act § 1201, 42 U.S.C. § 300gg-3 (2012) (prohibiting exclusion based on preexisting conditions as well as premiums tied to health status).

5. As described in this Article, waivers can be used to promote innovation by removing legal impediments. See *infra* notes 32–33 and accompanying text. At the same time, they can be used to preserve existing arrangements that do not comply with new requirements; when used in this way, waivers can retard innovation. But even this type of waiver can be viewed as promoting innovation if it lowers the costs of transitions or makes the underlying innovative mandate more feasible.

6. See Patient Protection and Affordable Care Act § 1332, 42 U.S.C. § 18052 (2012).

7. See Patient Protection and Affordable Care Act § 3022, 42 U.S.C. § 1395jjj (2012).

8. See Patient Protection and Affordable Care Act tit. III, pt. 3 (2010).

bundled so as to encourage more efficient delivery of care.<sup>9</sup> The ACA establishes the Center for Medicare and Medicaid Innovation to administer future demonstration projects. It will have a long-term mission of “test[ing] innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care.”<sup>10</sup> The ACA also establishes the Patient-Centered Outcomes Research Institute, which will alter the provision of care through research. Its mission is to “assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed.”<sup>11</sup>

Collectively, these examples demonstrate a much enhanced role for the federal government in fostering innovation in health care policy and practice. To some, this enhanced role might seem unusual. The federal bureaucracy is not often thought of as a leading source of innovation. Innovation in health care products and services is often thought to be the work of private individuals, companies, and provider organizations that, inspired by the prospect of financial rewards, professional recognition, or healthier or happier patients, find new ways to provide treatment. Innovation in health care policy is often thought to be the work of state governments. The metaphor of states as laboratories—generally attributed to a 1932 dissenting opinion in which Justice Brandeis noted that “[i]t is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country”<sup>12</sup>—suffuses the health policy literature.<sup>13</sup>

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9. See Patient Protection and Affordable Care Act § 3023, 42 U.S.C. § 1395cc-4 (2012).

10. See Patient Protection and Affordable Care Act § 3021, 42 U.S.C. § 1315a (2012).

11. See Patient Protection and Affordable Care Act § 6301, 42 U.S.C. § 1320e (2012).

12. *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). The importance of federalism for experimentation was recognized long before this opinion. Scott L. Greer & Peter D. Jacobson, *Health Care Reform and Federalism*, 35 J. HEALTH POL. POL'Y & L. 203, 207 (2010) (“Federalism enables a people to try experiments which could not safely be tried in a large centralized country.” (citation omitted)).

13. See generally, e.g., Randall R. Bovbjerg, Joshua M. Wiener & Michael Housman, *State and Federal Roles in Health Care: Rationales for Allocating Responsibilities*, in *FEDERALISM & HEALTH POLICY* 25–51 (John Holahan, Alan Weil & Joshua M. Wiener eds., 2003); Greer & Jacobson, *supra* note 12; Michael S. Sparer & Lawrence D. Brown, *States and the Health Care Crisis: Limits and*

The question that the ACA raises, then, is what the growing federal presence in the health care system means for a process of experimentation that has so often occurred at a more granular level. Part II of this Article describes the roles of the federal government, state governments, and health care providers in fostering health system experimentation. It suggests that the ACA's effect is not to displace other actors' contributions to innovation and evaluation, but instead to redirect them. Part III explores why these contributions may be in need of redirection. It examines factors that undermine providers' efforts to innovate and the shortcomings of the state-as-laboratory model of policy experimentation. It then details ways in which the ACA addresses these problems.

Part IV considers steps the federal government might take to build a better federal laboratory. It suggests three broad approaches. First, the federal government could spur more state policy innovation through funding programs that provide the same sort of financial incentives to states as those currently offered to private health care providers. Second, the federal government could facilitate policy evaluation either by applying different rules to different entities ("regulating with variation") or by offering a regulatory menu from which entities could choose. Finally, it could encourage more systematic analysis of innovations by conditioning waivers or regulatory exceptions on commitments to practices that facilitate evaluation, such as participation in randomized trials. Part V concludes.

## II. STATES AND DELIVERY SYSTEMS AS LABORATORIES

The ACA has been described by its opponents as a "federal takeover" of the health care system.<sup>14</sup> As a lengthy federal statute focused on health care,

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*Lessons of Laboratory Federalism*, in HEALTH POLICY, FEDERALISM, AND THE AMERICAN STATES 181–200 (Robert F. Rich & William D. White eds., 1996); Charles Barrilleaux & Paul Brace, *Notes from the Laboratories of Democracy: State Government Enactments of Market- and State-Based Health Insurance Reforms in the 1990s*, 32 J. HEALTH POL. POL'Y & L. 655 (2007); Howard Leichter, Commentary, *State Health Policy Analysis: On the Abuse of Metaphor and the Pathology of Variation*, 22 J. HEALTH POL. POL'Y & L. 897 (1997); Michael S. Sparer, *Laboratories and the Health Care Marketplace: The Limits of State Workforce Policy*, 22 J. HEALTH POL. POL'Y & L. 789 (1997).

14. See, e.g., *Sen Hutchison Calls for State Opt Out Amendment to Health Care*, KTRT, <http://www.ktre.com/story/12196113/sen-hutchison-calls-for-state-opt-out-amendment-to-health-care> (last visited Jan. 13, 2014); Robert Pear, *States Decide on Running New Pools for Insurance*, N.Y. TIMES (Apr. 29, 2010), [http://www.nytimes.com/2010/04/30/health/policy/30health.html?\\_r=0](http://www.nytimes.com/2010/04/30/health/policy/30health.html?_r=0) (quoting Georgia insurance commissioner as describing the high-risk insurance pool as "the first step

it certainly increases federal involvement in many aspects of the health care system. As this Part explains, however, the ACA still leaves room for states and health care providers to act as laboratories.

#### A. *States as Laboratories*

Scholars have devoted considerable effort to analyzing the roles of state and federal governments in the development and diffusion of health care policy.<sup>15</sup> Much of this literature refers to and amplifies upon the Brandeis state-as-policy-laboratory metaphor,<sup>16</sup> but the meanings that scholars attach to the metaphor vary. Michael Sparer and Lawrence Brown identify four “images” of state policy laboratories:

The first image is state officials and policy analysts working together to test theoretical policy hypotheses. The second is the image of states looking at and learning from other states, and adapting imported ideas to their own conditions. The third image pictures federal officials adopting national reforms that have been pioneered and tested in the states. The fourth, and most “lab-like,” image is that of social scientists studying state policy initiatives,

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in the recently enacted federal takeover of the United States health care system”).

15. See generally, e.g., Randall R. Bovbjerg, *Alternative Models of Federalism: Health Insurance Regulation and Patient Protection Laws*, in *FEDERALISM & HEALTH POLICY* 361–89 (John Holahan, Alan Weil & Joshua M. Wiener eds., 2003); Howard M. Leichter, *State Governments and Their Capacity for Health Care Reform*, in *HEALTH POLICY, FEDERALISM, AND THE AMERICAN STATES* 151–73 (Robert F. Rich & William D. White eds., 1996); Robert F. Rich & William D. White, *Health Care Policy and the American States: Issues of Federalism*, in *HEALTH POLICY, FEDERALISM, AND THE AMERICAN STATES* 3–33 (Robert F. Rich & William D. White eds., 1996); Carolyn Hughes Tuohy, *Variation in Health Care Policy in the American States: The Dog that Didn't Bark*, in *HEALTH POLICY, FEDERALISM, AND THE AMERICAN STATES* 203–17 (Robert F. Rich & William D. White eds., 1996); Robert F. Rich & William D. White, *Health Care Policy and the American States: Issues of Federalism*, in *HEALTH POLICY, FEDERALISM, AND THE AMERICAN STATES* (Robert F. Rich & William D. White eds., 1996); Carolyn Hughes Tuohy, *Variation in Health Care Policy in the American States: The Dog That Didn't Bark*, in *HEALTH POLICY, FEDERALISM, AND THE AMERICAN STATES* (Robert F. Rich & William D. White eds., 1996); Thomas J. Anton, *New Federalism and Intergovernmental Fiscal Relationships: The Implications for Health Policy*, 22 J. HEALTH POL. POL'Y & L. 691 (1997); Abigail R. Moncrieff, Essay, *Federalization Snowballs: The Need for National Action in Medical Malpractice Reform*, 109 COLUM. L. REV. 844 (2009).

16. See *supra* note 13.

evaluating programs, and suggesting improvements.<sup>17</sup>

These four images capture several different ways that states might be said to function as laboratories. First, they share a presumption that at least one state is willing and able to adopt an innovative policy. States cannot serve as laboratories unless some are mavericks. Second, all four images include references to testing or evaluation processes of some sort, and the first and fourth images highlight these processes. Finally, the second and third images focus on policy transmission. When one state adopts a new policy that appears to achieve some success, its model will be studied and may be replicated by other states as well as by the federal government.

States clearly have the potential to serve all of these functions. States frequently adopt innovative policies; these policies are often assessed in some way and then replicated at the state or federal level. Managed care regulations, for example, spread quickly from state to state.<sup>18</sup> Key health-related parts of the federal statutes COBRA<sup>19</sup> and HIPAA<sup>20</sup> can be traced to state initiatives, as can the federal Medigap program<sup>21</sup> and the federal diagnosis-related group hospital payment method.<sup>22</sup> In fact, the ACA can be traced to a state program: Massachusetts provided a model for the ACA's state-based exchanges as well as for its individual mandate.<sup>23</sup>

The ACA allows state laboratories to continue to operate in this way. While it imposes numerous mandates,<sup>24</sup> it offers states the flexibility

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17. Sparer & Brown, *supra* note 13, at 188–89.

18. See Bovbjerg, *supra* note 15, at 384.

19. Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-272, 100 Stat. 82 (1986).

20. Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

21. *Medigap (Medicare Supplement Health Insurance)*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/Medicare/Health-Plans/Medigap/index.html?redirect=/medigap> (last visited Jan. 14, 2014).

22. See Bovbjerg, *supra* note 15, at 384 (discussing COBRA, Medigap, and HIPAA); Bovbjerg, Wiener & Housman, *supra* note 13, at 42 (discussing diagnosis-related groups).

23. See generally Kavita Patel & John McDonough, *From Massachusetts to 1600 Pennsylvania Avenue: Aboard the Health Reform Express*, 29 HEALTH AFF. 1106 (2010) (describing Massachusetts health reform as a model for national reform). The Massachusetts health care reform that served as a model for the ACA was financed in part through subsidies associated with a federal Medicaid waiver, demonstrating how federal efforts to provide flexibility at the state level can benefit federal policymakers seeking to design new federal programs. See *id.* at 1108 (explaining waivers in Massachusetts).

24. See *supra* notes 1–4 and accompanying text.



necessary for experimentation.<sup>25</sup> Rather than creating a single national insurance program, it relies on states to implement policies and programs that will facilitate access to insurance coverage.<sup>26</sup> The ACA increases coverage for low-income individuals by retaining and expanding upon existing Medicaid programs, which are operated by the states under federal guidelines.<sup>27</sup> It permits states to design and operate the exchanges through which federal subsidies will flow to individual purchasers of insurance packages.<sup>28</sup> The federal government has now also turned to states to identify the essential health benefits that must be included in individual and small group insurance products.<sup>29</sup> Rather than specify the content of each of the ACA's ten mandated categories of health benefits through federal regulation,<sup>30</sup> the Department of Health and Human Services (HHS) has allowed states to define essential health benefits based on "benchmark" insurance plans offered within the state.<sup>31</sup> For each of these examples, the ACA and its associated federal regulations will impose some limits on what states can do, but states will be permitted to adopt innovative policies within these limits.

The ACA also allows for some state experiments through waivers.<sup>32</sup> Waivers facilitate innovation by freeing interested states from otherwise applicable statutory or regulatory requirements, allowing them to try different policy approaches. Some waivers are issued for reasons that have little to do with promoting experimentation,<sup>33</sup> but others are more clearly

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25. *See New Report Details Affordable Care Act Resources and Flexibility for States*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Feb. 25, 2011), <http://www.hhs.gov/news/press/2011pres/02/20110225a.html>.

26. *See id.*

27. *See The Medicaid Program at a Glance*, KAISER FAMILY FOUND. (Mar. 4, 2013), <http://www.kff.org/medicaid/upload/7235-04.pdf> (describing the Medicaid program generally); Patient Protection and Affordable Care Act § 2001, 42 U.S.C. 1396 (2012) (mandating expansion of the Medicaid program).

28. *See generally* Jon Kingsdale & John Bertko, *Insurance Exchanges Under Health Reform: Six Design Issues for the States*, 29 HEALTH AFF. 1158 (2010) (describing functions of exchanges).

29. *Id.*

30. *See* Patient Protection and Affordable Care Act § 1302(b)(1), 42 U.S.C. § 18022(b)(1) (2012) ("essential health benefits").

31. *Additional Information on Proposed State Essential Health Benefits Benchmark Plans*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.html> (last visited Jan. 14, 2014).

32. *See generally* Kingsdale & Bertko, *supra* note 28.

33. A number of ACA waivers appear to be intended to preserve the pre-ACA status quo, rather than to support future experimentation. *See* Robert Pear, *Four States Get Waivers to Carry Out*

directed at allowing regulated entities to pursue innovations that would otherwise run afoul of statutory or regulatory constraints.<sup>34</sup> The ACA takes this route when it allows states to seek broad waivers of requirements related to the operation of state health benefit exchanges as long as they meet certain minimum coverage requirements consistent with the ACA and do not increase the federal deficit.<sup>35</sup> It is not clear how many states will take advantage of such a waiver, but it is one that could support future experimentation.<sup>36</sup>

These are just a few of the many ways in which states continue to have a role in shaping health policy and health care delivery under the ACA. The motivation for preserving state flexibility may or may not include a desire to promote the development, evaluation, and diffusion of health system innovations. The reasons that the ACA and other federal programs are designed to accommodate state flexibility are undoubtedly both numerous

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*Health Law*, N.Y. TIMES (Feb. 16 2011), <http://www.nytimes.com/2011/02/17/health/policy/17health.html> (describing grant of waivers to Florida, New Jersey, Ohio, and Tennessee permitting insurers to provide plans with coverage more limited than ACA-required levels). For example, HHS has accepted some state requests for waivers of the ACA's minimum insurance coverage requirements, as well as some state requests for adjustments to the federal minimum loss ratio, which sets the threshold of medical spending below which insurance companies will be required to rebate a portion of premiums to their enrollees. *See id.*; *Medical Loss Ratios for Health Insurance*, NAT'L CONFERENCE OF STATE LEGISLATURES, <http://www.ncsl.org/research/health/health-insurance-medical-loss-ratios.aspx> (last updated June 20, 2013) (explaining loss ratio and providing a list of 2011 state waiver applications and results, amongst other information about waivers from medical loss ratio requirements); *Medical Loss Ratio*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/CCIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/Medical-Loss-Ratio.html> (last visited Jan. 15, 2014). A federal statute mandates rebates in the small group and individual markets when medical loss ratios fall below 80%, but allows the Secretary to "adjust such percentage with respect to a State if the Secretary determines that the application of such 80 percent may destabilize the individual market in such State." 42 U.S.C. § 300gg-18(b)(1)(A)(ii) (2012).

34. In an article from the mid-1990s, Elizabeth Andersen identified three types of Medicaid-related waivers: "(1) demonstration waivers, permitting short-term experimentation and analysis of innovative policies; (2) programmatic waivers, approving particular formulaic, longer-term policy changes; and (3) congressionally mandated waivers, implementing express congressional mandates regarding particular policy innovations." Elizabeth Andersen, *Administering Health Care: Lessons from the Health Care Financing Administration's Waiver Policy-Making*, 10 J.L. & POL. 215, 216–17 (1994).

35. *See* Patient Protection and Affordable Care Act § 1332, 42 U.S.C. § 18052 (2012) ("Waiver for State innovation").

36. For an argument that this waiver provision is a problematic approach to encouraging state innovation, see Stuart Butler, *The Wyden-Brown Bill—Short on State Flexibility*, 364 NEW ENG. J. MED. 397 (2011).

and varied, reflecting historical, practical, and political factors. Ultimately, however, regardless of its justifications, the ACA's reliance on state involvement in policy implementation leaves room for states to experiment and learn from one another's successes and failures.

### *B. Delivery Systems as Laboratories*

Much of Part II.A's discussion of state-led health system experimentation focused on Title I of the ACA, which contains requirements related to health coverage. Much of health care providers' discussion of the ACA, however, revolves around Title III. Entitled "Improving the Quality and Efficiency of Health Care," Title III contains a number of provisions intended to reform health care delivery.<sup>37</sup> While some states have actively encouraged delivery reform, states' laboratory functions tend to be more limited in this domain than in the health care coverage domain.<sup>38</sup> The laboratories that are most prominent in the health care delivery context are instead those that belong to health care providers.

The primary purpose of health care delivery systems is to provide medical care.<sup>39</sup> But, like states, delivery systems also serve as laboratories of policy experimentation in the sense that they sometimes adopt novel policies and practices, and the consequences of these reforms are sometimes evaluated by those seeking to improve their own policies and practices.<sup>40</sup> In fact, the parallels between delivery systems and scientific laboratories may be closer than the parallels between states and scientific laboratories, given

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37. For example, Title III's subtitles include Subtitle A, "Transforming the Health Care Delivery System," Subtitle B, "Improving Medicare for Patients and Providers," and Subtitle F, "Health Care Quality Improvements." Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

38. For examples of some state delivery reform initiatives, *see generally* S. Comm. on Health, Education, Labor & Pensions, Health Care Delivery System Reform and the Patient Protection & Affordable Care Act (2012) (report from Sen. Sheldon Whitehouse for the Committee), *available at* <http://www.whitehouse.senate.gov/imo/media/doc/Health%20Care%20Delivery%20System%20Reform%20and%20The%20Affordable%20Care%20Act%20FINAL2.pdf>; Nat'l Acad. for State Health Policy, Re-Forming Health Care Delivery Systems: A Summary of a Forum for States and Health Centers 10–16, *available at* <http://www.nashp.org/sites/default/files/hrsa.system.reform.pdf>; Nat'l Governors Ass'n, State Roles in Delivery System Reform 5 (2010), *available at* <http://www.nga.org/files/live/sites/NGA/files/pdf/1007DELIVERYSYSTEMREFORM.PDF>.

39. *See Lower Costs, Better Care: Reforming Our Health Care Delivery System*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 28, 2013), <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-Sheets/2013-Fact-Sheets-Items/2013-02-28.html>.

40. *See* HEALTH CARE DELIVERY SYSTEM REFORM, *supra* note 38, at 13–15.

the nature of medical practice. Delivery systems are generally staffed by scientifically trained health care providers and are sometimes affiliated with academic institutions—thus, delivery systems may sometimes be more attentive than state governments to the need to systematically study the impact of their reforms.

Why are health care delivery systems willing to serve as laboratories, adopting changes that may then be mimicked by other providers? First, providers may act from a simple desire to improve quality of life, either for themselves or for their patients. Second, physicians and other providers working within these systems have a professional obligation to deliver high quality care.<sup>41</sup> Third, individual and institutional providers may have an intrinsic desire to establish a reputation for offering high quality care.

Finally, providers may respond to outside pressures to alter health care delivery.<sup>42</sup> The most obvious kind of pressure is direct, command-and-control public regulation, or private regulation, such as hospital accreditation requirements.<sup>43</sup> Regulation can promote quality-improving and efficiency-enhancing change. But the more prescriptive the regulation is, the less room it leaves for future experimentation. A second form of outside pressure arises from market forces.<sup>44</sup> Payment mechanisms can be designed to reward quality and efficiency, increasing providers' incentives to reform their approaches to health care delivery; competition can further reinforce these incentives.<sup>45</sup> As long as these payment mechanisms allow for flexibility in delivery approaches, they can help to create an environment conducive to experimentation.<sup>46</sup>

While the federal government does impose some regulations on health

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41. One description of the principles of medical professionalism refers to the "primacy of patient welfare" and the "[c]ommitment to improving quality of care." Troy Brennan et al., *Medical Professionalism in the New Millennium: A Physician Charter*, 136 ANNALS INTERNAL MED. 243, 244–45 (2002).

42. See *infra* notes 43–46 and accompanying text.

43. See *Hospital Accreditation*, JOINT COMMISSION, <http://www.jointcommission.org/accreditation/hospitals.aspx> (last visited Jan. 16, 2014) (describing hospital accreditation program).

44. See Len M. Nichols, Paul B. Ginsburg, Robert A. Berenson, Jon Christianson & Robert E. Hurley, *Are Market Forces Strong Enough to Deliver Efficient Health Care Systems? Confidence Is Waning*, 23 HEALTH AFF. 8, 12 (2004) (discussing the effects of market forces on health care providers).

45. See *id.*

46. See *id.*

care providers participating in federal health care programs,<sup>47</sup> federal regulators are not permitted to “exercise any supervision or control over the practice of medicine or the manner in which medical services are provided” or “over the administration or operation” of providers in connection with the Medicare program.<sup>48</sup> The ACA does not eliminate this restriction. Instead of seeking to change patterns of medical care through direct regulation, it puts in place measures likely to encourage providers to alter their practices—an approach to health care delivery reform that Part III will discuss in more detail. For the purposes of this Part, the key point is simply that the ACA allows for a wide range of provider-initiated innovations in health care delivery systems. It permits provider-based experimentation to continue.

### III. BUILDING A FEDERAL LABORATORY

Part II of this Article suggested that the ACA takes advantage of states’ and health care providers’ traditional roles as laboratories by allowing them the freedom to develop innovative policies. But freedom does not always lead to experimentation. Flexibility permits but does not guarantee innovation. Similarly, flexibility does not guarantee and can even undermine the evaluation that is central to experimentation. This Part argues that by addressing weaknesses in the state-as-laboratory model of policy development, federal involvement can facilitate more systematic development and evaluation of beneficial policies and practices. At the same time, by addressing longstanding weaknesses in health care markets, federal involvement can foster greater innovation and evaluation in health care delivery. This Part discusses the steps that the ACA has taken in both of these directions, in effect building a federal laboratory that fosters experimentation nationwide.

#### *A. The Problems with State Laboratories*

Part II argued that the ACA provides the necessary flexibility for the policy diffusion contemplated by the state-as-laboratory metaphor. But the fact that states are given flexibility does not necessarily mean they will reach

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47. See, e.g., 42 C.F.R. § 482 (2013) (Medicare’s conditions of participation for hospitals).

48. 42 U.S.C. § 1395 (2012).

their full potential as laboratories.<sup>49</sup> To some, the laboratory metaphor might suggest that as long as states are permitted to innovate, a body of knowledge about policy effectiveness will begin to accumulate, just as scientific knowledge does. However, there are many ways in which the process of policy development, evaluation, and diffusion differs from the scientific process as it occurs in laboratory settings.<sup>50</sup> In thinking about the ideal federal role in health policymaking, it may be helpful to consider the limits to the state-as-laboratory metaphor.

How do laboratories ordinarily work? A laboratory is a physical setting in which experimentation occurs.<sup>51</sup> Scientists formulate hypotheses, design experiments to test these hypotheses, and then conduct these experiments in laboratories to better control the conditions under which experimentation<sup>52</sup> occurs. Careful controls help to contain experiments' effects within the laboratory, facilitate efforts to assess the impact of the scientist's interventions, and permit replication of experiments by others. After completing their experiments, scientists evaluate and report their laboratory experiments' results, allowing others to make use of the knowledge that has emerged.

Even this brief description of the process of experimentation suggests several ways in which the comparison of a state to a laboratory is inapt. To begin with, states may more closely resemble the scientists in this description than the laboratories. If "state officials and policy analysts work[] together to test theoretical policy hypotheses," as suggested by Sparer and Brown's first image of the state-as-laboratory metaphor, then innovative states may act like scientists in the sense that they seek to develop knowledge.<sup>53</sup> Consistent with this image, states do occasionally engage in

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49. See discussion *infra* Part III.A–B.

50. Michael Abramowicz, Ian Ayres & Yair Listokin, *Randomizing Law*, 159 U. PA. L. REV. 929, 949 (2011).

51. For a discussion of the nature of experiments, see Sparer & Brown, *supra* note 13, at 187 (discussing hypothesis testing in a laboratory setting, including the need for replication); James A. Gardner, *The "States-As-Laboratories" Metaphor in State Constitutional Law*, 30 VAL. U. L. REV. 475, 480–82 (1996) (discussing scientific experimentation); Peter S. Menell, *Regulating "Spyware": The Limitations of State "Laboratories" and the Case for Federal Preemption of State Unfair Competition Laws*, 20 BERKELEY TECH. L.J. 1363, 1373–75 (2005) (highlighting critical features of experimentation).

52. See Gardner, *supra* note 51, at 480.

53. See Sparer & Brown, *supra* note 13, at 188–89; see also *supra* note 17 and accompanying text (describing four images of states as laboratories).

formal policy experiments in which they test and evaluate the outcomes of particular policy approaches.<sup>54</sup>

More often, though, when observers refer to states as laboratories, they refer simply to situations in which states adopt novel laws or policies.<sup>55</sup> A state adopting an innovative policy could be analogized to a scientist formulating a novel hypothesis, and policy innovation could be analogized to hypothesis generation. But if the state does not then systematically test its hypothesis by evaluating the effects of its policy, the comparison between the state and scientist fails. A more appropriate label for the state in this scenario may be “experimental subject” or “laboratory rat.” Each state adopting a new policy essentially becomes an observation in a bigger experiment that will often involve multiple states. An outside researcher can gather information from innovating states and perhaps from other states in an attempt to ascertain the impact of the innovative policies.

There are a few senses in which states could be said to act as “laboratories” rather than as scientists or experimental subjects. First, if a state implements a policy that permits variation across geographic subunits such as cities or counties, the state as a whole can serve as a laboratory in the sense that its laws, regulations, and other statewide characteristics serve as controls for the experiment. Second, a state might be said to serve as a laboratory in the sense that a policy experiment is conducted within it, just as a scientific experiment is conducted within a physical laboratory. In some cases, consistent with Justice Brandeis’s view,<sup>56</sup> the policy experiment’s effects will be contained within the state’s borders, and these effects will generate information for outside observers just as laboratory experiments do.

Sparer and Brown’s four images of the state-as-laboratory metaphor—images that involve both the testing of policy innovations and their subsequent replication—could be said to implicitly capture all these roles for states: state as scientist, state as subject, and state as laboratory.<sup>57</sup> Indeed,

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54. See, e.g., Daniel Chandler et al., *Client Outcomes in Two Model Capitated Integrated Service Agencies*, 47 PSYCHIATRIC SERVICES 175 (1996) (describing and evaluating a pilot program that reformed the financing and delivery of mental health services in two California counties).

55. See, e.g., Keith Cunningham-Parmeter, *Forced Federalism: States as Laboratories of Immigration Reform*, 62 HASTINGS L.J. 1673, 1676 (2011) (discussing the use of the state-as-laboratory metaphor in the context of new state immigration laws and policies). Cunningham-Parmeter argues that states do not serve as effective laboratories in the immigration context. *Id.* at 1679.

56. See *New State Ice Co. v. Liebmann*, 285 U.S. 262, 310–11 (1932) (Brandeis, J., dissenting).

57. See Sparer & Brown, *supra* note 13, at 188–89.

the state-as-laboratory metaphor may be used to refer more generally to the entire scientific process, including the development of a hypothesis, the testing of that hypothesis, and the dissemination of the results of the test.<sup>58</sup>

This close examination of the state-as-laboratory metaphor yields two benefits. First, the observation that states may act as scientists or subjects rather than laboratories in this process is important because it suggests that the “laboratory” label might sometimes be a better fit for the country as a whole. If the nation is a laboratory and individual states are merely formulating hypotheses or participating in experiments, then it seems that the federal government might have an important role to play in ensuring the quality of experimentation.<sup>59</sup>

Second, this discussion invites a more careful look at not just the similarities between scientific experimentation and policy experimentation, but also the distinctions. The distinctions are numerous.<sup>60</sup> In fact, the distinctions arise even before the experimentation might be said to begin: While scientists are rewarded financially and professionally for producing knowledge through experimentation, states may not be. As a result, states are not always eager to engage in the innovation that is so integral to experimentation. Researchers have identified many impediments to innovation. Theoretical models suggest that rational politicians may be unwilling to undertake risky innovation.<sup>61</sup> Governments may be unwilling to

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58. See Gardner, *supra* note 51, at 480.

59. Other authors have highlighted the federal role in facilitating experimentation, although they offer differing views on that role. See, e.g., Shannon K. McGovern, *A New Model for States as Laboratories for Reform: How Federalism Informs Education Policy*, 86 N.Y.U. L. REV. 1519, 1549 & n.169 (2011) (stating that “[o]ne way to conceptualize the federal role is as a laboratory assistant who simultaneously observes and provides research support for a number of experiments, drawing inferences from the results and serving as an information repository for future experiments,” and contrasting that view with another author who advocates for a more expansive role for the federal government).

60. For a discussion of the distinctions between policy experimentation and scientific experimentation, see David A. Dana, *State Brownfields Programs as Laboratories of Democracy?*, 14 N.Y.U. ENVTL. L.J. 86, 97–100 (2005) (describing five elements of laboratory experiments and distinguishing them from states’ brownfields programs); Gardner, *supra* note 51, at 480–82 (explaining differences between policy and scientific experimentation and observing that the “image of scientific experimentation conjured up by the laboratories metaphor is misleading”); Menell, *supra* note 51, at 1373–75 (explaining the scientific method and its inapplicability to experiments in internet policy); Sparer & Brown, *supra* note 13, at 187 (contrasting hypothesis testing in a laboratory and in social science work).

61. See generally Susan Rose-Ackerman, *Risk Taking and Reelection: Does Federalism Promote Innovation?*, 9 J. LEGAL STUD. 593 (1980) (analyzing models of political risk taking).



engage in full experimentation because doing so would require some of them to adopt practices perceived to be less desirable than the status quo or other alternatives.<sup>62</sup> States have no incentive to take into account the informational benefits that their experiments will produce for others.<sup>63</sup> States may ultimately decide that it is better to rely on the results of experiments conducted (and funded) by others. Collectively, these considerations imply that states may experiment less than would be socially optimal.<sup>64</sup>

Abigail Moncrieff identifies another reason that states may not engage in policy reform as often as they should: federal programs that help out state residents interfere with states' incentives to innovate.<sup>65</sup> When the federal government takes on significant financial responsibility for state residents, states do not bear the full costs of their policies, and therefore will not reap the full financial benefit from reforming those policies.<sup>66</sup> As a result, they will be less inclined to engage in cost-reducing reforms than would be

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including that of a centralized system, a decentralized system, and a "federal" system).

62. See Edward L. Rubin & Malcolm Feeley, *Federalism: Some Notes on a National Neurosis*, 41 UCLA L. REV. 903, 925 (1994); see also Brian Galle & Joseph Leahy, *Laboratories of Democracy? Policy Innovation in Decentralized Governments*, 58 EMORY L.J. 1333, 1368–69 (2009) (discussing situations where states are reluctant to innovate because of a risk of lower returns than the status quo); cf. David A. Super, *Laboratories of Destitution: Democratic Experimentalism and the Failure of Antipoverty Law*, 157 U. PA. L. REV. 541, 566 (2008) (pointing to ethical concerns that arise when "some outcomes" of a democratic experiment "may be far more probable than others").

63. In addition, states have little incentive to account for the direct effects of their policies on other states. For a discussion of policy spillovers, see Moncrieff, *supra* note 15, at 868–72 (2009). If the spillovers are positive, states making decisions based purely on their own welfare will undersupply reforms relative to the social optimum.

64. Brian Galle and Joseph Leahy, after a thorough review and analysis of the literature on state policy innovation, conclude that "there is social underprovision of experimentation by small jurisdictions." Galle & Leahy, *supra* note 62, at 1370. Galle and Leahy examine a number of factors that might ensure continued state innovation, including the possibility that states may not be able to free ride when there are significant differences in state characteristics, see Galle & Leahy, *supra* note 62, at 1346–61; the possibility that there might be an advantage for the state that adopts an innovative policy first, *id.* at 1361–67; and the possibility that the differences in state policy goals and risk preferences will generate policy diversity, *id.* at 1369. They nevertheless reach the conclusion that policy experimentation will be undersupplied relative to the social optimum. *Id.* at 1398.

65. See generally Moncrieff, *supra* note 15 (discussing implications of federalization).

66. See *id.* at 847 ("While a given state fully internalizes the benefits of inefficient malpractice laws, that state does not bear the full cost of the inefficiencies. Instead, it externalizes a significant (and ever-growing) portion of those costs onto the federal government and, by extension, onto the other forty-nine states."); *id.* at 847–48.

efficient. Moncrieff illustrates this point with the example of medical malpractice. She argues that because the federal government funds health care through Medicare, Medicaid, tax breaks, and other programs, states are able to externalize the costs associated with their medical liability systems onto the federal government (such as the costs associated with defensive medicine).<sup>67</sup> For this reason, she argues, the federal government should take a more active role in malpractice and patient safety reform.<sup>68</sup> The same argument could be applied to any reform with health care cost implications, including state reforms of laws, regulations, and policies regarding health care cost, quality, and access. In short, federal involvement in financing health care means that states have suboptimal incentives to implement cost-reducing reforms.

Even when a state does choose to innovate, it may not produce knowledge that benefits other states. While scientific experiments are designed to generate knowledge by answering specific questions, states most often design and implement innovative policies in the hope of achieving a desired policy objective.<sup>69</sup> The goal of generating new knowledge is often secondary, if it exists at all.<sup>70</sup> A number of commentators have observed that states have little incentive to structure their policy experiments in ways that will generate data useful for other states.<sup>71</sup>

Even if a state is willing to share its data, the data may not reveal much about the impact of the program. The fundamental problem is that policy innovation does not take place within a laboratory, but within the real world, where it is difficult to implement adequate controls. Without adequate controls, researchers may not be able to determine whether an outcome resulted from the experimental intervention or from an unrelated variable.

Unable to directly control the environment in which an experiment occurs, social scientists have turned to a variety of methods to try to sort out causation. Occasionally, they test policies through randomized controlled

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67. See *id.* at 848–50 (summarizing argument).

68. See *id.* at 882–89 (proposing types of federal involvement).

69. See, e.g., Gardner, *supra* note 51, at 480–81 (describing goals in policy experimentation).

70. See *id.* at 481–82.

71. See, e.g., Galle & Leahy, *supra* note 62, at 1351 (“As [Rose-Ackerman] points out, information about an experiment that might prove useful to others is typically an externality for the experimenter.” (footnote omitted)); Abigail R. Moncrieff & Eric Lee, *The Positive Case for Centralization in Health Care Regulation: The Federalism Failures of the ACA*, 20 KAN. J.L. & PUB. POL’Y 266, 277 (2011); Rubin & Feeley, *supra* note 62, at 926.

trials.<sup>72</sup> More often, though, empirical researchers take advantage of natural experiments, tracking policies adopted by states and the possible outcomes the policies might influence.<sup>73</sup> They may compare the outcomes of individuals affected by a new policy to those of individuals not affected by the policy. Researchers can also use statistical techniques to control for other state-related factors that contribute to policy outcomes.

Applying these techniques in the policy setting can be challenging. Real-life reforms may be adopted after a change in conditions within the state, complicating efforts to distinguish the effects of the reform from the effects of the changed conditions. They may also involve multiple simultaneous innovations, complicating efforts to disentangle the impacts of each of the individual innovations. And while many analysts use regression techniques to control for state factors that might affect policy outcomes, the more relevant state factors that exist, the less successful this approach is likely to be; at some point, the number of relevant factors overwhelms the number of data points available to pin them down.<sup>74</sup> In an article advocating randomization of law, Michael Abramowicz, Ian Ayres, and Yair Listokin identify a number of problems associated with regression analyses, including omitted variable bias, which occurs when models omit factors that contribute to policy results, leading researchers to make incorrect inferences about the impact of the policy itself.<sup>75</sup> As the authors observe, “[t]he difficulties that social scientists and especially policymakers face in assessing the results of state innovations contribute to the inaptness of the states-as-laboratories metaphor.”<sup>76</sup>

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72. See DAVID GREENBERG ET AL., SOCIAL EXPERIMENTATION AND PUBLIC POLICYMAKING 37–40 (2003) (noting a decrease in federal funds and an increase in state funds for social experiments); Abramowicz et al., *supra* note 50, at 948 (noting that “randomized experiments have increasingly been conducted within states”).

73. See Michelle M. Mello & Kathryn Zeiler, *Empirical Health Law Scholarship: The State of the Field*, 96 GEO. L.J. 649 (2008) (reviewing methods for studying the impact of health law); Ryan W. Scott, *Inter-Judge Sentencing Disparity After Booker: A First Look*, 63 STAN. L. REV. 1, 24 (2010) (“Unlike a controlled experiment, in which researchers themselves change a condition to study its effects, a natural experiment examines the effects of exogenous changes that occur in the world without any prompting by researchers, such as the enactment of a new law or a series of Supreme Court decisions.”).

74. See Moncrieff & Lee, *supra* note 71, at 276–77 (citing “demographic and sociological diversity among the states” as the biggest limit “to the usefulness of state-based experiments”).

75. See Abramowicz et al., *supra* note 50, at 938–48. They also discuss problems of publication bias and model misspecification. See *id.* at 943–46.

76. *Id.* at 947.

In addition, idiosyncratic variations in policies preclude straightforward inferences about the effects of particular policy approaches. Robert Hurley and Stephen Zuckerman's discussion of federal waivers in the context of innovations in state Medicaid operations illustrates this problem.<sup>77</sup> In the 1980s and 1990s, many states sought "Section 1115" waivers of certain federal requirements in order to implement reforms in their Medicaid programs.<sup>78</sup> The waiver program attempted to overcome any reluctance states might otherwise have to share relevant information with others by imposing "detailed reporting and oversight requirements . . . designed to facilitate research and evaluation, thus generating knowledge."<sup>79</sup> However, by 1997, "[w]hile some new programs maintained a semblance of their original research and demonstration function, waivers increasingly authorized highly idiosyncratic models of reform and programmatic changes."<sup>80</sup>

Section 1115 waivers continue to provide an important outlet for state innovation and variation, supporting expansions in Medicaid coverage, modifications to payment mechanisms, and changes in delivery systems.<sup>81</sup> The more idiosyncratic and varied the models that Section 1115 waivers support, however, the harder it will be to establish the models' effects. In essence, the same flexibility that fosters innovation undermines evaluation.

In a more constrained world, there might be more examples of a particular type of innovative model. An increased number of observations may enhance researchers' ability to separate the effects of the model from the effects of other factors that might contribute to policy outcomes.<sup>82</sup> The Section 1115 programs may be effective demonstration programs in that

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77. Robert E. Hurley & Stephen Zuckerman, *Medicaid Managed Care: State Flexibility in Action*, in *FEDERALISM & HEALTH POLICY* 215, 220–22 (John Holahan, Alan Weil & Joshua M. Wiener eds., 2003).

78. *Id.* at 221.

79. *Id.* On the nature and use of Medicaid waivers under Section 1115 of the Social Security Act, see Madhu Chugh, *Executive Authority to Reform Health: Options and Limitations*, 37 J.L. MED. & ETHICS 22, 25 (2009) (stating that as of January 2007, there were 110 Medicaid and SCHIP Section 1115 waivers and that fourteen million beneficiaries received coverage through waiver programs). See generally Andersen, *supra* note 34 (describing Medicaid waiver programs).

80. Hurley & Zuckerman, *supra* note 77, at 222.

81. See *Five Key Questions and Answers About Section 1115 Medicaid Waivers*, KAISER FAMILY FOUND. (June 30, 2011), <http://kff.org/health-reform/issue-brief/five-key-questions-and-answers-about-section/>.

82. See Hurley & Zuckerman, *supra* note 77, at 227–30.

they permit observers to assess whether states can overcome the logistical challenges of implementing new policies.<sup>83</sup> Administrators can share their views about aspects of the program that seem to work well and aspects that do not. The programs are less well suited, however, to systematic, comparative evaluation.

Admittedly, policy evaluation does not always require randomized controlled trials. Books on program and policy evaluation are filled with advice on how to assess policy implementation in real-world settings, and the randomized controlled trial is just one of many options.<sup>84</sup> All are consistent with Sparer and Brown's fourth image of states as laboratories, which involves "social scientists studying state policy initiatives, evaluating programs, and suggesting improvements."<sup>85</sup> At the same time, however, the many limitations to these methods collectively mean that while states may try to learn from one another's experiences, they will often need to confront challenges that laboratory scientists do not face. The question, then, is whether increased federal involvement can help address these challenges.

#### *B. The Problems with Delivery System Laboratories*

Health care providers, like states, occasionally engage in experimentation. Hospitals, physicians, and other providers may innovate in the delivery of care, just as states may innovate in their financing or regulation of health care.<sup>86</sup> Hospitals may act like scientists, conducting studies in order to assess the impact of internal delivery reforms, or like experimental subjects, participating in multi-institutional experiments evaluated by outside researchers. Hospitals sometimes act as laboratories in

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83. *See id.*

84. *See, e.g.,* CAROL H. WEISS, EVALUATION 180–93 (2d ed. 1998) (describing different methods for evaluating programs and policy processes and outcomes). Both the approaches to evaluation and evaluation goals are highly varied. *See* MELVIN M. MARK, GARY T. HENRY & GEORGE JULNES, EVALUATION: AN INTEGRATED FRAMEWORK FOR UNDERSTANDING, GUIDING, AND IMPROVING POLICIES AND PROGRAMS 97 (2000) (describing the relationship between four "inquiry modes" of evaluation, "description," "classification," "causal analysis," and "values inquiry," and three purposes of evaluation, "oversight and compliance," "program and organizational improvement," and "knowledge development."). The limitations of states as laboratories may undermine some evaluation forms more than others.

85. Sparer & Brown, *supra* note 13, at 188–89.

86. *See* David M. Cutler, *Where Are the Health Care Entrepreneurs? The Failure of Organizational Innovation in Health Care* 15 (Nat'l Bureau of Econ. Research, Working Paper No. 16030, 2010).

the sense that they supply the setting for delivery reform innovation within their own walls. In all of these ways, delivery system laboratories could be said to resemble state laboratories.

Delivery systems laboratories also resemble state laboratories in that they may face suboptimal incentives to innovate.<sup>87</sup> Hospitals' incentives to innovate are likely weaker than those of for-profit entities in other industries.<sup>88</sup> Typically, for-profit producers engage in revenue-enhancing or cost-reducing innovations because doing so generates profits. When they find a way to increase the quality of a good, they may be able to raise prices and attract more customers; if they reduce production costs, they can undersell their competitors. Competitors facing a loss in customers may then respond with innovations of their own. The potential for profit associated with an innovation obviously depends on many factors, including the nature of the innovation and the nature of the underlying market, but the central point is simply that in many industries, innovation can lead to higher rewards.

Like providers of other goods and services, health care providers can and do innovate in quality-enhancing and cost-reducing ways. Physicians have a professional obligation to improve the quality of care for their patients, and health care providers must find ways to keep costs below reimbursement levels in order to remain afloat. But the characteristics of health care markets weaken the financial incentives that would otherwise exist for health care innovation.<sup>89</sup> One cause of market imperfections is the lack of information about health care quality.<sup>90</sup> Patients can judge the convenience and attractiveness of a facility, the attentiveness of providers, and certain other aspects of the care they receive. Patients are often not able to assess the clinical quality of their care, however. They generally cannot independently determine whether a provider's treatment recommendation was consistent with current medical knowledge, whether the outcome they experienced was due to the care delivered, or whether the outcome would

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87. See generally Sparer & Brown, *supra* note 13.

88. See Laura Landro, *The Time to Innovate Is Now*, WALL ST. J. (Mar. 28, 2011), <http://on.wsj.com/1e6jSHK> ("Unlike many other industries, health care has remained highly fragmented, with a hierarchical culture resistant to change, and a payment system that rewards providers for quantity rather than quality of care.").

89. The health economist David Cutler points to two factors that impede organizational innovation in health care: "lack of good information on quality" and "the stagnant compensation system of public insurance plans." Cutler, *supra* note 86, at 3.

90. See *id.*

have been better if another type of treatment had been given. Unless they find a way to overcome this information deficit, health care providers who do improve their quality may not be rewarded with an influx of patients.<sup>91</sup>

Providers who improve their quality may not be rewarded with higher prices, either. Patients are probably not willing to pay higher prices for an improvement in quality they cannot assess.<sup>92</sup> But even if they were willing to pay the higher price, it is often not the patient who pays the provider, but the patient's insurer.<sup>93</sup> Historically, payers have not been much better positioned than patients to assess quality and have not adjusted their payments to account for quality, instead paying fixed fees for whatever services were provided.<sup>94</sup> While a reputation for providing high quality care might generate bargaining power that translates into higher fees, such as when an insurer's customers insist that a particular hospital system be included in an insurer's network, this link between payment and quality is indirect and would be unlikely to strongly incentivize delivery innovations across a range of hospitals.<sup>95</sup> Without more direct ties between payment and quality, the financial incentive to engage in quality-enhancing innovation will be limited.

The nature of health care markets also limits provider incentives to innovate in cost-reducing ways. Health care providers face pressure to control costs for each service they provide, but this pressure may not extend to controlling total costs of treatment for a patient. Many service providers are compensated on a fee-for-service basis,<sup>96</sup> which means that as long as the compensation level is sufficiently high, they can increase profits by providing more services. Thus, while they have an incentive to economize on the costs of providing a given service, they might not have an incentive to reduce the number of services they provide.<sup>97</sup> Thus, current payment

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91. *See id.*

92. *See id.*

93. *See id.* at 25.

94. *See id.* at 3.

95. *See id.* at 21–22.

96. *See id.* at 20.

97. In addition, hospitals seeking to reduce costs face a further challenge: The physicians who make many decisions that influence hospitals' costs are often independent of the hospital and not the hospital's employees. *See* Gail B. Agrawal, *Resuscitating Professionalism: Self-Regulation in the Medical Marketplace*, 66 MO. L. REV. 341, 356–59 & n.78 (2001) (“Physicians influence or control approximately seventy-five percent of health care spending through their practice patterns.”); *id.* at n.78 (noting that “physicians are usually independent contractors, rather than employees” of

practices impede robust competition based on the total costs of treatment.

Other factors that might hinder innovation include the lack of provider competition in some markets and, in more competitive markets, the difficulty of preventing competitors from duplicating a successful innovation. Complex regulations can also slow innovation in the health care industry, as they do in other industries.<sup>98</sup> This partial list of barriers to health care delivery innovation hints at the magnitude of the difficulties involved in reforming the health care system. Delivery experiments, like state policy experiments, can be difficult to get started.

Some of the same problems that plague efforts to evaluate and disseminate information about state policies also appear in the health care delivery setting. An innovative hospital may have little incentive to share the evaluation of its results with other hospitals, for example. In addition, the same factors that impede innovation may reduce providers' commitment to evaluation. Evaluation will generate little financial return unless it is essential for making delivery changes that improve net revenues. If the nature of health care markets precludes such rewards, then other incentives must be used to support evaluation.

It is true that some aspects of the delivery system culture may make evaluation and information dissemination occur more readily in health care delivery than in health care policy. For example, by their very nature, teaching hospitals combine health care delivery with teaching and research functions; they may therefore be more inclined to systematically study the impact of health reforms. Nevertheless, the impediments to evaluation in the health care provider setting suggest that flexibility will not necessarily lead to full experimentation.

Thus, the shortcomings in delivery system experimentation raise the same question as the shortcomings in state experimentation: Can increased federal involvement in the health care system improve health system experimentation?

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managed care organizations). See generally Mark Hall, *Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment*, 137 U. PA. L. REV. 431 (1988). This independence restricts hospitals' ability to implement innovations that would reduce their own costs. See generally Hall, *supra* note 97.

98. See Regina A. Herzlinger, *Why Innovation in Health Care Is So Hard*, HARV. BUS. REV. (2006), <http://hbr.org/web/extras/insight-center/health-care/why-innovation-in-health-care-is-so-hard> (noting that sometimes government regulation can hinder innovation in health care).



*C. The ACA's Federal Laboratory*

Many of the ACA's provisions evidence a commitment to expanded federal involvement in health system innovation and research. For example, the ACA creates the Patient-Centered Outcomes Research Institute to "advanc[e] the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed."<sup>99</sup> But the ACA also contains a number of more targeted federal initiatives that appear designed to address some of states' and providers' shortcomings as laboratories, facilitating future experimentation. This subpart discusses these initiatives.

*1. Federal Support for Experiments Involving States*

As illustrated in Part III.A, the weaknesses of the state-as-laboratory model of policy experimentation include states' reluctance to innovate, their disinclination to develop and share information when they do innovate, and their tendency to adopt highly varied policies that have the effect of obscuring the relationship between policy features and policy outcomes.

The ACA works to overcome states' suboptimal incentives to innovate in two ways: mandates and subsidies. If the federal government sought to increase access to care by enacting a single-payer system or requiring that everyone purchase individual insurance from a nationally regulated insurer, there would be little reason or room for states to find innovative ways to increase access. But, as discussed in Part II, the ACA preserves a significant role for states in increasing their residents' access to care. For example, under the ACA, states will develop and operate health benefit exchanges through which individuals and small businesses will be able to purchase health insurance.<sup>100</sup> By defining basic features of the exchanges, but leaving states much discretion with respect to exchange operations, the ACA will tend to engender variation in state approaches and leave room for state innovation.

The federal government has also provided financial support to states seeking to innovate in connection with the ACA. By lowering the cost of

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99. Patient Protection and Affordable Care Act § 6301, 42 U.S.C. § 1320e (2012).

100. See Patient Protection and Affordable Care Act § 1311(b)(1), 42 U.S.C. § 18031(b)(1) (2012).

innovation, the ACA helps promote innovation.<sup>101</sup> The ACA provides grants for states to use in the development of exchanges,<sup>102</sup> and HHS gave “Early Innovator” grants to support states’ efforts to build the information technology infrastructure of these exchanges—infrastructure that could then be “adopted and tailored by other states.”<sup>103</sup> Rewarding early innovators in this way incentivizes greater production of innovation and encourages faster dissemination of information. The ACA also subsidizes state innovation through funding for demonstration programs operated at the state level. For example, it authorizes funding for state demonstration projects involving the “development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations.”<sup>104</sup>

While funding for demonstration projects clearly plays an important role in supporting state innovation, so does the mere existence of federally defined demonstration projects. Federal demonstration projects involving states are perhaps the clearest example of a federal laboratory at work. The constraints fashioned by the federal government to define demonstration projects focus states’ attention on particular goals and mechanisms for achieving those goals.<sup>105</sup> In essence, the constraints determine the hypothesis to be tested. The constraints also facilitate efforts to test the hypotheses by permitting more systematic evaluation of the impact of innovations that states adopt.<sup>106</sup> In these ways, the impact of demonstration projects can extend beyond what might be achieved by simply permitting

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101. Analysts who recognize that states may have suboptimal incentives to innovate have suggested awarding prizes to encourage further innovation. *See* Galle & Leahy, *supra* note 62, at 1361 (citing Rose-Ackerman, *supra* note 61, at 615–16, for the observation “that a centralized planner can prompt innovation by offering grants or prizes to local innovators, presumably in amounts tied to the approximate size of the externality they produce,” as well as other sources’ ideas for rewarding local experimentation).

102. *See* Patient Protection and Affordable Care Act § 1311(a), 42 U.S.C. § 18031(a) (2012).

103. *See States Leading the Way on Implementation: HHS Awards “Early Innovator” Grants to Seven States*, U.S. DEP’T OF HEALTH & HUMAN SERVS. (Feb. 16, 2011), <http://www.hhs.gov/news/press/2011pres/02/20110216a.html>.

104. Patient Protection and Affordable Care Act § 10607, 42 U.S.C. § 280g-15 (2012).

105. *See* Abbe R. Gluck, *Intrastatutory Federalism and Statutory Interpretation: State Implementation of Federal Law in Health Reform and Beyond*, 121 YALE L.J. 534, 589–92 (2011).

106. *Cf.* Moncrieff & Lee, *supra* note 71, at 283 (arguing that “fully nationalizing” Medicaid funding under the ACA, which was not done, would have replaced “haphazard[]” state experimentation with “a thoughtfully structured process to produce and replicate good policy nationwide”).

states the flexibility to innovate.<sup>107</sup>

A number of commentators have recognized both the potential contributions of states that innovate and the potential benefits of the involvement of some centralized authority in coordinating states' efforts. Rubin and Feeley, for example, note that a central authority seeking to determine which policy would achieve a particular objective could "order different sub-units to experiment with different strategies until the best way to achieve the goal emerges."<sup>108</sup> This approach would use a mandate to overcome states' reluctance to innovate, while at the same time permit more systematic evaluations of policies than is possible when states innovate in an ad hoc way.<sup>109</sup> Abramowicz, Ayres, and Listokin similarly envision a regime in which governments could operate experiments across geographic areas. They argue that "government should embrace randomized trials of statutes and regulations as a tool for testing the effectiveness of those laws"<sup>110</sup> and note that "it may be possible to randomize policies across states, at least among states that consent."<sup>111</sup>

As the ACA illustrates, however, the federal government is more likely to turn to demonstration programs or pilot projects than to randomized controlled trials as a way of advancing experimentation.<sup>112</sup> For example, under one demonstration program, state Medicaid programs will use bundled payments to pay for the care of beneficiaries.<sup>113</sup> States seeking to participate in the demonstration must specify the episodes of care and specific services to be included in the program, but the Secretary is permitted to modify these parameters and to vary them across participating states.<sup>114</sup> In other words,

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107. See Gluck, *supra* note 105; Moncrieff & Lee, *supra* note 72, at 283.

108. Rubin & Feeley, *supra* note 62, at 924.

109. See generally Rubin & Feeley, *supra* note 62, at 924 (explaining why federalism is not conducive to scientific experimentation and the kinds of coordination that would be necessary to engage in robust experimentation). They conclude that "[i]t is thus hardly surprising, even given the most favorable assumptions about the rationality and conscientiousness of state governments, that most significant 'experimental' programs in recent years have in fact been organized and financed by the national government." *Id.* at 925.

110. Abramowicz et al., *supra* note 50, at 933.

111. *Id.* at 948.

112. Federal regulatory experiments do sometimes occur; Abramowicz, Ayres, and Listokin have discussed an example involving the Securities and Exchange Commission. See Abramowicz et al., *supra* note 50, at 988–91.

113. Patient Protection and Affordable Care Act § 2704 ("Demonstration project to evaluate integrated care around a hospitalization"), 42 U.S.C. § 1396a note (2012).

114. Patient Protection and Affordable Care Act § 2704(b)(3), 42 U.S.C. § 1396a note (2012).

states are permitted to innovate, but the federal government may impose constraints that could be used to improve the quality of experimentation.<sup>115</sup>

Other state-based demonstration projects involve Medicaid global capitation payments to safety-net hospitals,<sup>116</sup> malpractice liability reform,<sup>117</sup> and insurer-sponsored wellness programs.<sup>118</sup>

The ACA did not invent the demonstration project—demonstrations have long been used as mechanisms to test new approaches to health system reform.<sup>119</sup> The ACA took a clear step toward supporting greater growth in demonstration projects, however, by establishing the Center for Medicare and Medicaid Innovation (CMI), which will “test innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care”<sup>120</sup> and by appropriating ten billion dollars for its operations from 2011 to 2019.<sup>121</sup> This dedicated funding will substantially increase the federal government’s ability to conduct policy experiments.<sup>122</sup>

Perhaps equally important, the ACA grants the HHS Secretary

115. See, e.g., *id.*

116. Patient Protection and Affordable Care Act § 2705 (“Medicaid Global Payment System Demonstration Project”), 42 U.S.C. § 1315a note (2012).

117. Patient Protection and Affordable Care Act § 10607 (“State demonstration programs to evaluate alternatives to current medical tort litigation”), 42 U.S.C. § 280g-15 (2012).

118. Patient Protection and Affordable Care Act § 2705(1) (“Wellness Program Demonstration Project”), 42 U.S.C. § 300gg-4 (2012).

119. See, e.g., COMM. ON RAPID ADVANCE DEMONSTRATION PROJECTS: HEALTH CARE FINANCE & DELIVERY SYS., BD. ON HEALTH CARE SERVS., INST. OF MED. OF THE NAT’L ACADS., *FOSTERING RAPID ADVANCES IN HEALTH CARE: LEARNING FROM SYSTEM DEMONSTRATIONS* (Janet M. Corrigan, Ann Greiner & Shari M. Erickson eds., 2002), available at <http://faculty.law.miami.edu/mcoombs/documents/CoombsFosteringRapidAdvancesinHealthCare.pdf> (proposing a series of demonstration projects involving primary care delivery information technology, insurance coverage, and state liability reform).

120. Patient Protection and Affordable Care Act § 3021(a)(1), 42 U.S.C. § 1315a(a)(1) (2012). The mission of CMI is to “produce better experiences of care and better health outcomes for all Americans at lower costs through improvements.” Karen VanLandeghem, *Innovation Center Established to Improve Health Outcomes and Reduce Costs*, ASS’N OF MATERNAL & CHILD HEALTH PROGRAMS, <http://www.amchp.org/AboutAMCHP/Newsletters/Pulse/Archive/2011/March2011/Pages/Feature3.aspx> (last visited Jan. 17, 2014). See generally *The CMS Innovation Center*, CTRS. FOR MEDICARE & MEDICAID SERVS., [innovations.cms.gov/](http://innovations.cms.gov/) (last visited Jan. 17, 2014).

121. See VanLandeghem, *supra* note 120; Patient Protection and Affordable Care Act § 3021, 42 U.S.C. § 1315a(f) (2012).

122. See Robert Mechanic & Stuart Altman, *Medicare’s Opportunity to Encourage Innovation in Health Care Delivery*, 362 NEW ENG. J. MED. 772, 773 (2010) (noting the importance of the large appropriation for effective operations).

significant authority in managing demonstration projects—authority that may increase the projects’ ultimate impact on policy.<sup>123</sup> Historically, demonstration projects have been challenging to initiate because they require political as well as financial support to create and administer.<sup>124</sup> Given the time-consuming nature of project approval, creation, operation, and formal evaluation, many years may pass between the initial conception of a project and the reporting on its results, potentially limiting the usefulness of the project.<sup>125</sup> Even when projects seem to have been successful, Congress has not always responded by making policy changes.<sup>126</sup>

Policy analysts suggest that the ACA may help to address these problems.<sup>127</sup> First, under the ACA, the Secretary would have the authority to select particular models to be tested from a group of models that “address[] a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.”<sup>128</sup> This authority allows the Secretary the freedom to direct government resources toward the reform approaches deemed to be the most promising in the current environment, rather than being restricted to focusing on specific statutorily-mandated projects.<sup>129</sup> Second, the ACA prohibits the Secretary from

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123. See, e.g., Patient Protection and Affordable Care Act § 3021, 42 U.S.C. § 1315(a)(1) (2012).

124. See Michael S. Barr et al., *Lessons for the New CMS Innovation Center from the Medicare Health Support Program*, 29 HEALTH AFF. 1305, 1305 (2010) (noting that “CMS already has the authority to conduct demonstrations and pilot programs” but that “the agency’s activities to date have been limited by a host of political, legal, and budgetary constraints”); William M. Sage, *Why Are Demonstrations of Comprehensive Malpractice Reform So (At All) Controversial?*, 37 U. MEM. L. REV. 513, 526 (2007) (discussing barriers to creating federal malpractice demonstration projects).

125. See Stuart Guterman et al., *Innovation in Medicare and Medicaid Will Be Central to Health Reform’s Success*, 29 HEALTH AFF. 1188, 1190 (2010) (discussing the lengthy timelines involved in typical demonstration projects).

126. See Mechanic & Altman, *supra* note 122, at 772 (describing congressional failure to expand Medicare’s bypass surgery global fee demonstration).

127. See Barr et al., *supra* note 124, at 1305 (stating that the ACA “strengthens the CMS’s authority and capacity to foster innovation” and “addresses some of the historical boundaries placed on the agency”).

128. Patient Protection and Affordable Care Act § 3021, 42 U.S.C. § 1315a(a)(1) (2012).

129. See Chris Fleming, *Health Affairs Blog Roundtable Transcript: CMS and Health Reform*, HEALTH AFFAIRS BLOG (Apr. 29, 2010), <http://healthaffairs.org/blog/2010/04/29/health-affairs-blog-roundtable-transcript-cms-and-health-reform/> (quoting Bruce Vladeck, former administrator of the Health Care Financing Administration, as saying that “for the first time really since the early 1980s CMS is going to have the resources to essentially do noncongressionally mandated experimentation and program development”); Mechanic & Altman, *supra* note 122, at 773 (contrasting CMI’s “broad authority to select the programs best suited to its objectives” with “CMS’s Office of Research, Development, and Information,” which “has far less flexibility, because a large proportion of its

requiring models to be budget neutral during the initial testing phase; neutrality requirements had hampered previous demonstrations.<sup>130</sup> Third, the ACA requires the Secretary to terminate or modify models in some circumstances,<sup>131</sup> a requirement that analysts suggest “gives the CMS greater flexibility to design and develop new models.”<sup>132</sup> At the same time, the ACA allows the Secretary to expand the duration and scope of the model in other circumstances,<sup>133</sup> which will facilitate quicker and more widespread adoption of successful pilot programs.<sup>134</sup> Thus, CMS and its demonstration projects will likely play an even more important role in the future in fostering innovation across states and across delivery systems.<sup>135</sup>

Waivers and demonstration projects are important not just for encouraging innovation, but also for promoting evaluation and increasing the likelihood that knowledge generated by the innovation diffuses across the country. Some sort of evaluation component is typically part of waiver and demonstration programs. In a previously funded series of malpractice-related demonstration projects, for example, grant recipients were “required to submit patient safety data to [the federal Agency for Healthcare Research and Quality’s] network of patient safety databases” using pre-specified formats.<sup>136</sup> This kind of requirement not only ensures the availability of data for direct evaluation, but also facilitates comparisons across different projects, by standardizing data collection.<sup>137</sup>

The ACA imposes a number of waiver- and demonstration-related reporting requirements. Any state that takes advantage of the ACA’s broad

resources are devoted to congressionally mandated projects.”).

130. Patient Protection and Affordable Care Act § 3021, 42 U.S.C. § 1315a(b)(3)(A) (2012); *see also* Barr et al., *supra* note 124, at 1305; Mechanic & Altman, *supra* note 122, at 773 (referring to neutrality requirements).

131. Patient Protection and Affordable Care Act § 3021, 42 U.S.C. § 1315a(b)(3)(B) (2012).

132. Barr et al., *supra* note 124, at 1305.

133. Patient Protection and Affordable Care Act § 3021, 42 U.S.C. § 1315a(c) (2012).

134. *See* Mechanic & Altman, *supra* note 122, at 772 (“This provision is critical, because the need for congressional approval has delayed or derailed past initiatives.”).

135. The ACA contemplates that CMI will launch pilot programs testing both state-based reforms (such as state all-payer payment reform) and health care delivery reforms (such as payment reform for diagnostic imaging services). *See* Patient Protection and Affordable Care Act § 3021, 42 U.S.C. § 1315a(b)(2)(B)(vi), (xi) (2012).

136. *Fact Sheet: Patient Safety and Medical Liability Reform Demonstration*, WHITE HOUSE (Sept. 17, 2009), [http://www.whitehouse.gov/the\\_press\\_office/fact-sheet-patient-safety-and-medical-liability-reform-demonstration](http://www.whitehouse.gov/the_press_office/fact-sheet-patient-safety-and-medical-liability-reform-demonstration).

137. *See id.*

waiver in order to implement the state's own program for expanding coverage, for example, must submit periodic reports concerning program implementation, and the Secretary must conduct periodic evaluations of such programs.<sup>138</sup> States seeking to participate in the ACA demonstration project involving bundled payments to Medicaid providers must provide "relevant data necessary to monitor outcomes, costs, and quality."<sup>139</sup>

The ACA requires evaluations of models tested by CMI. Specifically, it authorizes the Secretary to impose data collection and reporting requirements on demonstration participants and requires the Secretary to analyze the "quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary" and "the changes in spending under the applicable titles by reason of the model."<sup>140</sup> It also requires evaluation results to be made publicly available.<sup>141</sup> These requirements will help to ensure an effectively functioning federal laboratory.

## 2. Federal Support for Delivery System Experimentation

In many ways, the federal support for delivery system experimentation resembles its support for state experimentation. The ACA relies heavily on demonstration projects and pilot programs, for example, as mechanisms to promote innovation and assure evaluation.<sup>142</sup> It establishes a pilot program on payment bundling under which a group of health care providers "including a hospital, a physician group, a skilled nursing facility, and a home health agency" would receive a bundled payment covering services delivered in conjunction with a patient's episode of care, beginning several days before hospital admission and extending thirty days following a patient's discharge.<sup>143</sup> This kind of pilot program could address providers' current disincentives to reduce treatment costs, an issue discussed in Part

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138. Patient Protection and Affordable Care Act § 1332(a)(4)(B)(iv)–(v), 42 U.S.C. § 18052(a)(4)(B)(iv)–(v) (2012).

139. Patient Protection and Affordable Care Act § 2704(d), 42 U.S.C. § 1396a note (2012).

140. Patient Protection and Affordable Care Act § 3021(b)(4)(A)(i)–(ii), 42 U.S.C. § 1315a(b)(4) (2012) (the word "titles" is changed to "subchapters" in the U.S. Code version).

141. Patient Protection and Affordable Care Act § 3021, 42 U.S.C. § 1315a(b)(4)(B) (2012).

142. See, e.g., Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2704(a), 124 Stat. 119, 323–24 (2010); *id.* § 3023.

143. *Id.* § 3023(c)(2)(A), 42 U.S.C. § 1395cc-4(c)(2)(A) (2012).



## III.B.

The ACA also creates a demonstration program “to test a payment incentive and service delivery model that utilizes physician and nurse practitioner directed home-based primary care teams designed to reduce expenditures and improve health outcomes.”<sup>144</sup> Many of the models that the ACA proposes for testing by CMI involve health care delivery reforms, so much of the discussion in Part III.C.1 is actually even more relevant for delivery system experimentation than for state experimentation.<sup>145</sup>

Other ACA provisions, some of which build on earlier federal policies, are more squarely aimed at health care market features that undermine health care providers’ incentives to innovate. Part III.B highlighted two such features: the difficulty of assessing health care quality and the fact that payment often does not reflect quality. The ACA includes numerous provisions intended to enhance quality reporting.<sup>146</sup> In addition to requiring reporting in connection with specific demonstration projects, it mandates the development and public reporting of health care quality measures more generally.<sup>147</sup> In addition to potentially facilitating providers’ efforts to identify and address quality problems, public reporting may provide reputational and financial incentives to do so.<sup>148</sup> The ACA also takes a more

144. Patient Protection and Affordable Care Act § 3024, 42 U.S.C. § 1395cc-5(a)(1) (2012).

145. Patient Protection and Affordable Care Act § 3021, 42 U.S.C. § 1315(a)(b)(2)(B) (2012). Examples include “[c]ontracting directly with groups of providers of services and suppliers to promote innovative care delivery models, such as through risk-based comprehensive payment or salary-based payment,” and “[e]stablishing community-based health teams to support small-practice medical homes by assisting the primary care practitioner in chronic care management, including patient self-management, activities.” Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3021(b)(2)(B)(ii), (viii), 124 Stat. 119, 390–91 (2010).

146. See, e.g., Patient Protection and Affordable Care Act § 3002, 42 U.S.C. § 1395w-4 (2012) (improvements to physician quality reporting); *id.* § 3004, 42 U.S.C. § 1395ww (2012) (quality reporting for long-term care hospitals, inpatient rehabilitation hospitals, and hospice programs); *id.* §§ 3013–15 (codified in scattered sections of 42 U.S.C. 299 (2012)) (provisions on quality measurement and public reporting).

147. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 3013–15, 124 Stat. 119, 381–88 (2010) (codified in scattered sections of 42 U.S.C. 299 (2012)) (provisions on quality measurement and public reporting).

148. See Kristin Madison, *The Law and Policy of Health Care Quality Reporting*, 31 CAMPBELL L. REV. 215, 215–26 (2009) (discussing nature and benefits of report card use). Congress did not identify the specific quality measures to be used for reporting or value-based payment purposes. See *cf.* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2701, 124 Stat. 119, 317 (2010) (“Adult health quality measures”). With respect to public reporting, there is a statutory requirement that “[t]he Secretary shall report quality measures of process, structure, outcome, patients’ perspectives on care, efficiency, and costs of care that relate to services furnished in



direct route to incentivizing quality-enhancing delivery innovations: it contains pay-for-performance provisions that tie Medicare payments to quality measures for hospitals, physicians, skilled nursing facilities, and other providers.<sup>149</sup> These provisions focus institutional attention on improving health care delivery, without dictating specific mechanisms for quality improvement, thus preserving health care providers' ability to innovate.

#### IV. BUILDING A BETTER FEDERAL LABORATORY

Permitting state policy variation, financing and conducting demonstration projects, addressing market information failures, and altering provider payment mechanisms are all good ways to foster innovation and evaluation in the health care system. The federal government could do more, however, to build a federal laboratory. This Part explores additional approaches to encouraging the development, evaluation, and diffusion of policies and practices that increase health care access, reduce cost, and enhance quality.

##### A. Policy Incentives

Building on several years of federal experience with quality reporting and value-based purchasing, the ACA relies heavily on payment mechanisms to encourage delivery system reform. By altering payment formulas, it incentivizes providers to identify and implement strategies for increasing efficiency or improving the quality of care.<sup>150</sup>

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inpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services." 42 U.S.C. § 1395ww(b)(3)(B)(viii)(VII) (2012). With respect to value-based payments to hospitals, the ACA requires that measures cover acute myocardial infarction, heart failure, pneumonia, surgeries (as measured by the Surgical Care Improvement Project), and infections (as measured by the HHS Action Plan to Prevent Healthcare-Associated Infections), as well as consumer views as represented in the Hospital Consumer Assessment of Healthcare Providers and Systems survey. See 42 U.S.C. § 1395ww(o)(2)(B)(i)(I) (2012).

149. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3001, 124 Stat. 119, 122 (2010) (hospital value-based purchasing); *id.* § 3006 (skilled nursing facility and home health agency value-based purchasing); *id.* § 3007 (physician services value-based payment modifiers); *id.* § 3008 (payment adjustments for hospital-acquired conditions).

150. Regulations for Medicare's hospital value-based purchasing program give a glimpse of how such incentives might be structured. See *generally* Medicare Program; Hospital Inpatient Value-Based Purchasing Program, 76 Fed. Reg. 26,490 (May 6, 2011) (to be codified at 42 C.F.R. pts. 422

In theory, similar sorts of incentives could be used to encourage more innovation in state health policy. Congress has often promoted the adoption of particular policies through its funding formulas. One well-known example is its withholding of a portion of highway funds from states that permit the purchase of alcohol by people under the age of twenty-one.<sup>151</sup> Structurally, this sort of program could be said to resemble value-based purchasing programs that rely on process measures of quality. The hospital value-based purchasing program incentivizes timely administration of antibiotics, a step that might improve treatment outcomes;<sup>152</sup> the highway funding program incentivizes the adoption of a policy prohibiting alcohol sales to those under twenty-one, a step that might reduce highway accidents. This sort of program makes the most sense when the federal government has identified a policy change that it believes will benefit the public, but for some reason states have failed to adopt it on their own.

When the best approach to achieving a policy objective is unclear, or when it varies across states, financial incentives tied to policy outcomes may be more appropriate. One illustration of an outcome-based incentive can be found within the Race to the Top program for educational reform. Financed by the American Recovery and Reinvestment Act of 2009, the Race to the Top program offers over four billion dollars in grants to states choosing to adopt innovative programs to improve education.<sup>153</sup> The application guidelines for the competitive grant program specify a variety of selection criteria. Most are the equivalent of structure or process quality measures, although the application does not delineate specific steps that states must take. For example, points are allotted for “[f]ully implementing a statewide longitudinal data system” and “[i]ntervening in the lowest-achieving

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& 480). The regulations tie payment to process-related quality measures (such as whether antibiotics were received within one hour before surgery), as well as measures based on a consumer survey. *See id.* at 26,515–16. They will also include three outcome-based quality measures (such as thirty day mortality for heart attacks) in 2014. *Id.*

151. *See* 23 U.S.C. § 158 (2012) (“The Secretary shall withhold 10 per centum of the amount required to be apportioned to any State . . . in which the purchase or public possession in such State of any alcoholic beverage by a person who is less than twenty-one years of age is lawful.”).

152. *See generally*, DEP’T OF HEALTH & HUMAN SERVS., HOSPITAL VALUE-BASED PURCHASING PROGRAM (2013), available at [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Hospital\\_VBPurchasing\\_Fact\\_Sheet\\_ICN907664.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Hospital_VBPurchasing_Fact_Sheet_ICN907664.pdf) (explaining the benefits of the hospital value-based purchasing program).

153. U.S. DEP’T OF EDUC., RACE TO THE TOP PROGRAM EXECUTIVE SUMMARY 2 (2009), available at <http://www2.ed.gov/programs/racetothetop/executive-summary.pdf>.

schools.”<sup>154</sup> The application also refers to outcome measures: 30 of 500 possible points are allotted for “[d]emonstrating significant progress in raising achievement and closing gaps” based on measures such as high school graduation rates and national testing results.<sup>155</sup> In short, the Race to the Top program offers to state policymakers financial incentives based on structure, process, and outcome measures of educational quality.

Within the health care area, the Children’s Health Insurance Program Reauthorization Act of 2009 (CHIPRA) offers a similar sort of performance bonus to states.<sup>156</sup> To encourage greater enrollment of uninsured children in Medicaid, the legislation tied financial incentives both to the adoption of particular practices intended to increase enrollment and to the achievement of enrollment targets.<sup>157</sup> Federal officials have described this incentive as a “first-of-its-kind payment incentive for states . . . that offset[s] some of the costs associated with states’ success in covering more children in Medicaid.”<sup>158</sup> To be eligible for the bonus, states must implement five of eight specified practices, such as eliminating asset tests for eligibility, eliminating requirements for in-person interviews, and using a joint application for Medicaid and the Children’s Health Insurance Program.<sup>159</sup> States meeting these requirements could receive a bonus for every enrolled child above a target threshold; the target was calculated by first adjusting 2007 enrollment by child population growth and then increasing this number by several percentage points.<sup>160</sup> In 2011, nearly three hundred million dollars was awarded to twenty-three states that met the relevant criteria.<sup>161</sup>

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154. *Id.* at 3.

155. *Id.* at 3, 7.

156. Children’s Health Insurance Program Reauthorization Act of 2009, Pub. L. No. 111-3, 123 Stat. 8.

157. See *Children’s Health Insurance Program Reauthorization Act of 2009 (CHIPRA)*, KAISER FAMILY FOUND. (Feb. 12, 2009), <http://kff.org/health-reform/fact-sheet/childrens-health-insurance-program-reauthorization-act-of/> (describing CHIPRA).

158. INSUREKIDSNOW.GOV, CHILDREN’S HEALTH INSURANCE REAUTHORIZATION ACT ONE YEAR LATER: CONNECTING KIDS TO COVERAGE 5 (2010), available at <http://ccf.georgetown.edu/wp-content/uploads/2012/02/chipra-anniversary-report-final.pdf>.

159. *Id.* at 10 n.22.

160. See KAISER COMM’N ON MEDICAID & THE UNINSURED & GEORGETOWN UNIV. HEALTH POLICY INST. CTR. FOR CHILDREN & FAMILIES, CHIP TIPS: MEDICAID PERFORMANCE BONUS 2 (2009), available at [http://ccf.georgetown.edu/wp-content/uploads/2012/03/Federal%20schip%20policy\\_chip%20tip%20perf.%20bonus.pdf](http://ccf.georgetown.edu/wp-content/uploads/2012/03/Federal%20schip%20policy_chip%20tip%20perf.%20bonus.pdf).

161. See Julian Pecquet, *Obama Administration Awards \$300 Million for Children’s Health Care*, THE HILL (Dec. 28, 2011), <http://thehill.com/blogs/healthwatch/health-insurance/201581->

There is no similar provision in the ACA for state health policy reform. The ACA encourages state innovation by giving states flexibility in implementing federal requirements and funding demonstration projects, but it does not rely on tailored financial incentives as a way to encourage the adoption or diffusion of innovative policies. It is true that federal funding of the ACA's programs will affect state policies, as federal funding directed to states always has. To obtain Medicaid funding, for example, states must comply with federal mandates dictating the structure of their Medicaid programs.<sup>162</sup> But these federal payments do not generally vary with state policy "processes" in the same way that reimbursement will vary with hospital health care delivery processes. Nor does the ACA contain any provisions that link federal financial support specifically to state health policy outcomes.

What might a federal incentive for state health policy adoption look like? Consider health benefit exchanges. Federal regulations could continue to define some basic structural features of health exchanges while preserving significant flexibility in order to accommodate innovation. But Congress might simultaneously promise increased federal funding to states that find a way to increase the number of insured residents above a defined threshold, similar to the target already in place under CHIPRA.<sup>163</sup> This approach would give states the regulatory flexibility that many of them have called for, while at the same time holding the states accountable for the policy objectives Congress sought to achieve through the ACA.<sup>164</sup> Through the use

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obama-administration-awards-300-million-for-childrens-healthcare.

162. See 42 U.S.C. 1396(b) (2012) ("Payment to States").

163. See *supra* notes 156–60 and accompanying text.

164. Another example of an area in which the federal government could tie payment to quality metrics is Medicaid. Under the health reform statute, private Medicare Advantage plans will receive payments based on their "star ratings," which are in turn based on measures related to the provision of care, such as screening and vaccination rates, as well as measures related to customer service and member satisfaction. See Health Care and Education Reconciliation Act of 2010 § 1102(b)–(c), 42 U.S.C. § 1395w-23 (2012); see also REACHING FOR THE STARS: QUALITY RATINGS FOR MEDICARE ADVANTAGE PLANS, 2011, KAISER FAMILY FOUND. (2011), available at <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8151.pdf> (describing the rating system). If similar types of ratings were extended to Medicaid programs, then program administrators would have a financial incentive to focus on areas in need of improvement. Some Medicaid programs have already begun to institute reimbursement mechanisms for Medicaid providers that take into account quality metrics. See generally KATHRYN KUHMERKER & THOMAS HARTMAN, COMMONWEALTH FUND, PAY-FOR-PERFORMANCE IN STATE MEDICAID PROGRAMS (2007), available at <http://www.commonwealthfund.org/Publications/Fund-Reports/2007/Apr/Pay-for-Performance-in-State-Medicaid-Programs--A-Survey-of-State-Medicaid-Directors-and-Programs.aspx>. For an

of policy incentives, the federal government could increase the reward that individual states receive from effective policy reform, helping states overcome barriers that might otherwise impede innovation.

Outcome-oriented incentives in the state policy setting, like outcome-based quality measures in the health care delivery setting, would raise many substantive policy concerns.<sup>165</sup> Identifying an easily collectible and verifiable metric that accurately reflects policy objectives may be difficult. An incentive that directs focus toward a particular objective may divert focus from other, equally desirable objectives. States may engage in practices that help them achieve the defined target but undermine other policy goals. The details of how targets are defined will make it easier for some states to achieve the targets than others, inviting political conflict over target criteria. Note, however, that given the tremendous variation in state circumstances, any policy directed at states could be said to impact one state more than another. These concerns about the implications of outcome-oriented incentives suggest that the domains in which such incentives might be appropriate are limited, but incentives nevertheless may have the potential to encourage innovative state efforts to achieve federally defined policy objectives.

### *B. Regulatory Variation and Regulatory Menus*

When federal policymaking displaces state laboratories, it not only shuts down a major source of innovation, but also eliminates the variation that so often provides a foundation for evaluating an innovation's effects. Waivers and demonstration projects can help to address this problem, as can various statistical methods of evaluation, such as differences-in-differences analyses that compare the differences in pre-policy and post-policy outcomes between groups differentially impacted by a policy. But another approach would be to adopt a federal mandate that preserves variation in a purposeful way. As Abramowicz, Ayres, and Listokin suggest, randomization is one way to

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example of a program supporting value-based purchasing, see *Value-Based Purchasing*, MEDICAID.GOV, <http://www.medicaid.gov/State-Resource-Center/MAC-Learning-Collaboratives/Value-Based-Purchasing.html> (last visited Jan. 19, 2014). Presumably, federal subsidies tied to metrics would encourage more such contracting.

165. See generally Madison, *supra* note 148, at 226–36 (discussing problematic aspects of quality report cards).

build a foundation for studying the effects of policy approaches.<sup>166</sup>

Consider, for example, the ACA's menu labeling requirements.<sup>167</sup> Just a few years before the ACA was enacted, states such as California<sup>168</sup> and Maine<sup>169</sup> and cities such as New York<sup>170</sup> and Philadelphia<sup>171</sup> mandated that certain restaurants include nutrition-related information on their menus. A few studies have now been published assessing the impact of these early reporting requirements.<sup>172</sup> The details of the study designs vary, but most share a common structure: they compare pre-labeling behavior with post-labeling behavior in areas subject to a menu labeling requirement, while also examining behavior in areas not subject to the requirement. Information from mandate-free areas is important because it reveals trends influencing behavior apart from the labeling requirement. Because the ACA imposes a requirement for chain restaurants to display calorie information nationwide,<sup>173</sup> preempting state and local laws with different nutrition labeling requirements,<sup>174</sup> it may eliminate these mandate-free areas, complicating future research efforts in this area.<sup>175</sup> In short, while research

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166. See Abramowicz et al., *supra* note 50, at 974–1005 (discussing how randomization might be incorporated into policies).

167. Patient Protection and Affordable Care Act § 4205, 21 U.S.C. § 343 (2012).

168. CAL. HEALTH & SAFETY CODE § 114094 (West, Westlaw through 2013 Reg. Sess.).

169. See ME. REV. STAT. ANN. tit. 22, § 2500-A (West, Westlaw through 2013 1st Reg. Sess. and 1st Spec. Sess. of 126th Leg.).

170. N.Y.C., N.Y., HEALTH CODE § 81.50 (2014).

171. PHILA., PA., HEALTH CODE § 6-308 (2010).

172. See, e.g., Bryan Bollinger et al., *Calorie Posting in Chain Restaurants*, 3 AM. ECON. J.: ECON. POL'Y 91, 92 (2011) (finding that after calories were posted in compliance with the New York City menu mandate, average calories per transaction at Starbucks fell by 6%); Brian Elbel et al., *Calorie Labeling and Food Choices: A First Look at the Effects on Low-Income People in New York City*, 28 HEALTH AFF. w1110, w1117 (2009) (failing to find that menu labeling changed purchasing patterns); Eric A. Finkelstein et al., *Mandatory Menu Labeling in One Fast-Food Chain in King County, Washington*, 40 AM. J. PREVENTIVE MED. 122, 126 (2011) (finding that menu labeling did not affect purchases).

173. Patient Protection and Affordable Care Act § 4205(b), 42 U.S.C. § 343(q)(5) (2012).

174. Patient Protection and Affordable Care Act § 4205(c), 21 U.S.C. § 343-1(a)(4) (2012); U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: QUESTIONS AND ANSWERS REGARDING THE EFFECT OF SECTION 4205 OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT OF 2010 ON STATE AND LOCAL MENU AND VENDING MACHINE LABELING LAWS (2010), available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm223408.htm> [hereinafter *Guidance for Industry*].

175. FDA regulations allow states and localities to petition for exemptions from preemption, so some variation in labeling requirements is possible. See *Guidance for Industry*, *supra* note 174 (stating that “[s]tate and local governments cannot directly or indirectly impose any nutrition

on the effectiveness of labeling will certainly continue, the ACA's push toward uniformity will increase the difficulty of discerning the effects of menu labeling requirements.

How might this result have been avoided? In theory, Congress could have mandated a gradual implementation of nationwide labeling requirements, rather than imposing an immediate, universal mandate. Researchers could then try to discern the impact of reporting by comparing early-mandate areas to late-mandate areas. A variation on this approach would be to mandate nationwide disclosure, but to vary its content. Restaurants in some areas could be required to disclose calories, for example, while restaurants in other areas could be required to disclose calories and sodium content. Researchers could then examine whether the disclosure of sodium had no effect, had the intended effect of reducing sodium consumption, or had an unintended effect, such as an increase in calorie consumption, which might occur if restaurant goers' attention to caloric content were diverted as a result of information overload. After a few years of variation, regulatory uniformity could be imposed.

Whether the staggered mandate approach would successfully establish the necessary conditions for plausible inference depends on many factors. One such factor is the procedure used to ensure variation. Assigning implementation dates or reporting requirements by any mechanism other than random selection increases the likelihood that differences in comparison groups stem from differences in their characteristics rather than differences in the regulations imposed. A second factor is the behavior of the regulated entities. National restaurant chains may oppose staggered mandates out of a desire to preserve national uniformity in their restaurants. If such a scheme were nonetheless implemented, chains may choose to adopt the more stringent reporting requirements nationwide, undermining research

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labeling requirements on chain retail food establishments that are not 'identical to' requirements imposed by section 4205" but that "FDA's regulations, at 21 C.F.R. 100.1, allow any State or locality to petition FDA for an exemption from preemption"). The regulations state that "[t]he agency may grant the exemption . . . if the agency finds that the State requirement will not cause any food to be in violation of any applicable requirement under Federal law, will not unduly burden interstate commerce, and is designed to address a particular need for information that is not met by the preemptive Federal requirement." 21 C.F.R. § 100.1(a)(2) (2013). It is not clear, however, how many communities will take advantage of this option. In addition, communities that seek exemptions are likely to be quite different from those that do not, undermining efforts to use such variations to isolate labeling's effects from effects associated with characteristics of communities that adopt labeling.

efforts that depend on the continued existence of a robust control group.<sup>176</sup> A third consideration is that legislators might be reluctant to adopt staggered mandates because they would clearly evidence a willingness to impose mandates despite the existence of considerable uncertainty about their effects.

Even if it is not feasible to directly impose variation via statute, it may be possible to obtain variation via regulation. Consider menu labeling once again. In the course of implementing the menu labeling requirements, the FDA has had to make numerous choices about regulatory details, some of which may influence labeling's effectiveness. In the preamble to its proposed menu labeling regulations, for example, the FDA explained that in its earlier draft guidance, it had recommended that a food's calorie information have the "same color and contrasting background as the standard menu item."<sup>177</sup> It then noted that it had received comments suggesting that this approach would make calorie information less prominent and responded by proposing that calories must be posted "in the same color, or a color at least as conspicuous as the name of the associated standard menu item, and with the same contrasting background as the name of the associated standard menu item."<sup>178</sup> The FDA also discussed such quandaries as whether to require listings of average calories or ranges of calories when foods have multiple flavors or varieties, as well as what kind of statement about daily caloric consumption might be best suited for providing context for the calorie listings.<sup>179</sup> These choices are quandaries because they might have an impact on restaurant goers, but the nature of their impact is unclear.

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176. An effort to prohibit restaurants from disclosing additional nutritional information about their food, in order to preserve full regulatory variation, might be met with a First Amendment challenge. Under the *Central Hudson* test for governmental restrictions on commercial speech, the analysis would seem to turn on whether the government's interest in experimentation is substantial, whether the prohibition directly advances this interest, and whether the regulation is narrowly tailored to serve this interest. See *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 564 (1980).

177. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Food Establishments, 76 Fed. Reg. 19,192, 19,206 (proposed Apr. 6, 2011) (to be codified at 21 C.F.R. pts. 11 and 101).

178. See *id.* at 19,233.

179. See *id.* at 19,207–09 (discussing calorie averages and ranges); see also *id.* at 19,210. Two of the statements considered by the FDA were "[u]sing 2,000 calories per day as a reference point, consider how the menu item you select fits within your total daily calorie needs, which may be higher or lower depending on age, physical activity, gender" and "[a] 2,000 calorie daily diet is used as the basis for general nutrition advice; however, individual calorie needs may vary." *Id.* at 19,210.



Regulators could try to resolve a few of these quandaries through regulatory variation. Imagine that instead of requiring a color that is “at least as conspicuous,”<sup>180</sup> or requiring the presentation of calorie ranges, or selecting the shortest possible disclosure statement, the FDA conducted a multiyear randomized controlled trial in which different restaurants were required to comply with different requirements. For example, some restaurants might initially be required to present calorie ranges for different flavors, while others would be required to present averages. Information about consumer understanding and consumption decisions could then be collected and evaluated, allowing regulators to make a more informed selection of a particular approach to presenting calorie information. The FDA could randomize its requirements across states or across metropolitan areas on the grounds that variation would permit greater study of the impact of different features of menu labeling in a real-world setting.

Alternatively, it might be possible for the FDA to create a limited “regulatory menu” from which regulated entities could choose the regulatory approach they preferred. The idea of a regulatory menu is not new. Under the federal “meaningful use” regulations, for example, providers seeking financial incentive payments in connection with their adoption of electronic health records must meet criteria defined by regulation, but must also meet five additional objectives that they can select from a longer list of possibilities.<sup>181</sup> However, the purpose of the meaningful use menu of objectives is to allow flexibility for providers, not to create a potential foundation for research.<sup>182</sup> By contrast, the purpose of the regulatory menu suggested here would be to allow for the creation of a limited number of comparison groups to facilitate research on the effects of regulatory choices.

If the regulatory choices were structured in such a way that different entities would choose to subject themselves to different regulations, the resulting variation might permit further study. Regulatory menus would make the most sense in situations in which the likely impact of a particular approach is so unclear that the resulting “assignment” of entities to regulatory approaches is essentially random. For example, some restaurants might have a slight preference for the shorter statement about daily caloric

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180. *Id.* at 19,206.

181. *See* Medicare and Medicaid Programs; Electronic Health Record Incentive Program, 75 Fed. Reg. 44,314, 44,327 (July 28, 2010) (codified at 42 C.F.R. pts 412, 413, 422, and 495).

182. *Id.* (“We believe that establishing both a core and a menu set adds flexibility and allows the minimum statutory set to be met.”).

consumption because it fits their existing menu format better, while others might have a slight preference for the longer statement because they believe a longer statement would cause information overload and thus would weaken the impact of calorie disclosures. As long as these two groups are not systematically different (beyond their relative needs for menu space), their choices would generate data that would help to inform regulators about the implications of daily intake statements.

From the perspective of a researcher seeking to gather information about the impact of a regulation, regulatory menus would not be as attractive as regulation with variation. The worry is that whatever factors lead to an entity's choice of regulatory option may also contribute to regulatory outcomes in unobservable ways, obscuring the effect of the regulation itself.<sup>183</sup> However, menus do have the advantage of preserving some flexibility for regulated entities in contexts where regulators' preferences for a particular approach are not strong.

Like state laboratory-based experimentation, regulatory menu-based experimentation could potentially generate useful information because of the variation it allows. But unlike state laboratories, regulatory menus are subject to the control of a single experimenter. The FDA could maintain the same presentation format across all menu choices, but vary the daily intake statement; alternatively, it could vary the presentation format, but maintain uniformity in the daily intake statement. A state laboratory experiment might produce fifty menu formats, while a regulatory menu constrains the choices to two. Such constraints have the benefit of increasing the number of jurisdictions that would take any given approach, improving regulators' ability to make meaningful comparisons across jurisdictions. If each jurisdiction were to implement its own unique menu labeling law, as sometimes happens when states act as laboratories, then it would be difficult to sort out statistically which particular features of the labeling laws were generating each jurisdiction's outcomes.<sup>184</sup>

The ACA's preemption of state and local menu labeling requirements

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183. If the groups were systematically different, but in ways that could be observed, it may be possible to account for these differences in evaluating the results of the experiment.

184. For an examination of variation in state menu labeling requirements, see Ashley Arthur, Note, *Combating Obesity: Our Country's Need for a National Standard to Replace the Growing Patchwork of Local Menu Labeling Laws*, 7 IND. HEALTH L. REV. 305, 313–20 (2010) (deconstructing menu labeling requirements in New York, California, Washington, Pennsylvania, and Indiana).

suggests that the legislation was intended to achieve national uniformity in labeling mandates, facilitating national chain restaurants' efforts to maintain menu consistency.<sup>185</sup> Mandated variation would be inconsistent with that intent, although only in the short term while experimental data was being gathered. Regulatory menus would be less problematic if all restaurants in a chain were permitted to choose the same menu option. The main argument here, however, is not that regulatory variation is feasible or even desirable in the case of federal menu labeling requirements. Instead, the argument is simply that it may sometimes be desirable to enact federal statutes that permit regulatory variation or regulatory menus, at least for a limited period of time, in order to improve researchers' ability to conduct careful studies of regulatory effects.

### *C. Conditioned Waivers*

Regulatory variation facilitates evaluation by giving federal regulators the systematic variation they need to conduct their own policy experiments. These approaches make the most sense when regulators have already settled on a short list of reasonable, well specified policy choices, but are uncertain about which policy would generate the best result: should a shorter daily calorie intake statement be used or a longer, more detailed one? In many settings, however, particularly ones involving the most innovative policies, it will be difficult to develop a short list. In addition, political or practical concerns may mean that federal policymakers are reluctant to take responsibility for this type of broad experiment. An alternative approach would be to encourage voluntary experimentation and evaluation on a smaller scale, via conditioned waivers. Regulatory waivers could be conditioned on regulated entities' willingness to design, participate in, and disclose to regulators (or the public) the results of a study, with the basic parameters defined either as part of the waiver application process or through criteria specified by regulation.

Accountable care organizations (ACOs), which have been described as "networks of physicians and other providers that could work together to improve the quality of health care services and reduce costs for a defined

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185. Cf. *Guidance for Industry*, *supra* note 174.

patient population,”<sup>186</sup> provide an illustration of circumstances under which conditioned waivers might be useful. Under the ACA, ACOs that meet certain requirements are entitled to keep a portion of any Medicare savings they are able to generate through their management of care for a defined group of Medicare beneficiaries.<sup>187</sup> To function effectively, ACOs may need to form relationships and engage in practices that implicate existing fraud and abuse laws.<sup>188</sup> The ACA addresses this issue by giving the Secretary of Health and Human Services the authority to waive certain fraud and abuse statutory requirements “as may be necessary to carry out the provisions of this section.”<sup>189</sup>

The ACA did not specify the form that waivers should take.<sup>190</sup> In anticipation of the development of waiver-related regulations, health care practitioners discussed a number of options.<sup>191</sup> One approach would be to grant waivers based on a review of the risks and benefits of individual proposed arrangements.<sup>192</sup> The Office of the Inspector General of the Department of Health and Human Services has historically engaged in a similar process, in which it reviews potentially problematic arrangements described by providers, considers their purposes and risks, and then determines whether their adoption would be grounds for administrative sanction.<sup>193</sup> This case-by-case approach has the advantage of allowing regulators to scrutinize the details of particular arrangements, facilitating

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186. Mark Merlis, *Accountable Care Organizations (Updated)*, HEALTH AFFAIRS (Aug. 13, 2010), [http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief\\_id=23](http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=23).

187. See 42 U.S.C. § 1395jjj (2012).

188. See Merlis, *supra* note 186 (discussing legal barriers ACOs may face).

189. 42 U.S.C. § 1395jjj(f) (2012).

190. See 42 U.S.C. § 1395jjj(b)(3)(B) (2012).

191. See generally DOUGLAS A. HASTINGS ET AL., AM. HEALTH LAWYERS ASS'N, WAIVERS UNDER THE MEDICARE SHARED SAVINGS PROGRAM: AN OUTLINE OF THE OPTIONS (2010), available at <http://www.healthlawyers.org/hlresources/PI/Policy/Pages/ACOWaivers-OptionsOutline.aspx>.

192. See *id.* at 4–5.

193. See *Advisory Opinions*, OFFICE OF INSPECTOR GENERAL: U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://oig.hhs.gov/compliance/advisory-opinions/index.asp> (last visited Jan. 21, 2014). An example of a response: “[w]e conclude that . . . while the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the Office of Inspector General . . . will not impose administrative sanctions . . .” Re: OIG Advisory Op. No. 11-16 (Dep’t of Health & Human Servs. Nov. 8, 2011), available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-16.pdf>.

more concrete assessments of risks and benefits.<sup>194</sup> This approach also brings to everyone's attention specific examples of arrangements that might appeal to other providers and examples that might be helpful for policymakers refining fraud and abuse laws in the future.<sup>195</sup> It has the disadvantage of imposing significant costs on both applicants and regulators.<sup>196</sup>

A second approach is to issue blanket waivers for particular types of arrangements.<sup>197</sup> Regulators would describe the particular setting in which the waiver would apply, enumerating any criteria that must be satisfied beyond the general criteria for participation in the ACO program. This approach may be less costly for both ACOs and regulators, since there is no need to develop or review detailed, formal requests for waivers. It allows for a wide variety of ACO arrangements, and it provides a measure of regulatory certainty for entities considering forming new arrangements. For regulators, the challenge in creating appropriate waiver criteria is to anticipate the types of arrangements that ACOs might want to adopt under a waiver and then select criteria that will ensure that the newly allowed arrangements will promote the ACO program's objectives without raising the concerns underlying the fraud and abuse laws.

Federal regulators decided to adopt the blanket waiver approach.<sup>198</sup> They issued an interim final rule defining five sets of circumstances in which entities establishing or operating ACOs would be entitled to waivers of certain fraud and abuse laws.<sup>199</sup> Mindful of the risks that such blanket waivers might create, they indicated that the waivers would be narrowed over time

unless the Secretary determines that information gathered through monitoring or other means suggests that such waivers have not had the unintended effect of shielding abusive arrangements. In

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194. See HASTINGS ET AL., *supra* note 191, at 4–5.

195. See *id.*

196. See *id.* The exhaustive attention given to one particular case is not a feasible standard for every case. See, e.g., *id.*

197. See *id.* at 5–6.

198. See generally Medicare Program; Final Waivers in Connection with the Shared Savings Program, 76 Fed. Reg. 67,992, 67,999 (Nov. 2, 2011), available at <http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27460.pdf> (to be codified at 42 C.F.R. ch. V).

199. See generally *id.*

particular, if we find that undesirable effects (for example, aberrant patterns of utilization) have occurred because of the waivers, we will revise this IFC to address those problems by narrowing the waivers.<sup>200</sup>

Regulators will be able to monitor many types of utilization based on the claims data generated as part of the Medicare program.<sup>201</sup> They will also have access to information about treatment quality that ACOs are required to report.<sup>202</sup> Attributing abnormal utilization patterns or undesirable quality effects to abusive arrangements, however, would require a detailed follow-up investigation into the nature of the arrangements used and an analysis of potential links between the arrangements, health care costs, and outcomes.<sup>203</sup>

To facilitate both innovation and evaluation in health care delivery, regulators might have instead taken a third approach: a waiver conditioned on an entity's willingness to serve as a laboratory. By conditioning waivers on a commitment to data reporting, analysis, or both, regulators could shift at least some of the responsibility for evaluation of promising but potentially problematic arrangements to the parties involved, while simultaneously allowing for considerable flexibility in ACO implementation.

Consider the waiver granted for ACO beneficiary inducements.<sup>204</sup> To improve patient health and reduce expenditure growth, and to fulfill the statutory requirement of promoting patient engagement,<sup>205</sup> ACOs may want to use financial incentives that encourage behavioral change. ACOs might want to reward patients for adherence to a physician's recommended treatment regimen, for example. But ACOs might also be tempted to reward patients for seeking care from ACO providers—a practice that might improve patient health by facilitating ACOs' efforts to manage care internally, but might also interfere with competition with non-ACO

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200. *Id.* at 68,008 (footnote omitted).

201. *See id.* at 68,004, 68,008.

202. *See* Patient Protection and Affordable Care Act § 3022, 42 U.S.C. 1395jjj(b)(3) (2012).

203. *See, e.g.,* Medicare Program; Final Waivers in Connection with the Shared Savings Program, 76 Fed. Reg. 67,992, 68,008–09 (Nov. 2, 2011), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27460.pdf> (to be codified at 42 C.F.R. ch. V).

204. *See* Medicare Program; Final Waivers in Connection with the Shared Savings Program, 76 Fed. Reg. 67,992, 67,993, 67,995, 67,999 (Nov. 2, 2011), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27460.pdf> (interim final rule with comment period; to be codified at 42 C.F.R. ch. V).

205. *See* Patient Protection and Affordable Care Act § 3022, 42 U.S.C. 1395jjj(b)(2)(G) (2012).

providers. In addition, if it increases the total amount of care sought, the practice might increase Medicare program costs. To avoid these sorts of negative effects, an existing federal statute prohibits remuneration to Medicare beneficiaries that is “likely to influence [the beneficiary] to order or receive [a service] from a particular provider” if the service is covered by Medicare.<sup>206</sup>

Striking a balance between the potential risks and benefits of beneficiary inducement, the ACO regulations allow ACOs to provide beneficiaries free or reduced-price goods or services, but only under specified circumstances.<sup>207</sup> Among other requirements, the goods or services must be in-kind, have a reasonable connection to the patient’s care, and be preventive or advance one of four clinical goals, such as adherence to a treatment regime.<sup>208</sup> In adopting this rule, regulators rejected suggestions that ACOs should not receive a special waiver for beneficiary inducements.<sup>209</sup> They also rejected suggestions that ACOs should be permitted to use other kinds of financial incentives, such as reduced or eliminated patient cost-sharing requirements.<sup>210</sup> In addition, regulators left some specific questions to be answered, such as whether “preventive care” should be defined by regulation.<sup>211</sup>

By structuring the ACO program rules and related waivers differently, regulators could have allowed for more innovation in the nature of incentives offered and more information about these incentives’ effects. Imagine, for example, a waiver that would permit ACOs to use incentives of the sort permitted under the actual regulations, but only for a random subset of the beneficiaries assigned to them. Or, alternatively, imagine a waiver that would permit ACOs to eliminate co-payments for a subset of their

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206. 42 U.S.C. § 1320a-7a(a)(5) (2012).

207. *See* 42 U.S.C. § 1320a-7a(i)(6)(G), (H) (2012).

208. *See* Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67,958 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425). The interim final rule for ACO waivers contained the same provisions. *See* Medicare Program; Final Waivers in Connection with the Shared Savings Program, 76 Fed. Reg. 67,992, 68,001 (Nov. 2, 2011), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27460.pdf> (to be codified at 42 C.F.R. ch. V).

209. *See* Medicare Program; Final Waivers in Connection with the Shared Savings Program, 76 Fed. Reg. 67,992, 67,999 (Nov. 2, 2011), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27460.pdf> (to be codified at 42 C.F.R. ch. V).

210. *See id.*

211. *See id.* at 68,007.

patients to encourage adherence, but only if they provided a similarly valued in-kind incentive for adherence by a different subset of patients.

In either case, the ACO could be required to specify the precise nature of the incentives involved, define the group of patients eligible for the incentives, and identify the patients who actually received these incentives. It could further be required to identify and report on clinical measures that would allow for assessment of whether the incentives had had the intended health effect. HHS could then supplement this patient-specific data with quality and utilization data it already collects to determine whether the incentive seems to have had unintended effects. Essentially, the ACO could be asked to randomize its patients, then pass along the data generated by the experiment as a condition of receiving a waiver of fraud and abuse laws otherwise applicable to its use of incentives.

A permutation on this proposal would be to allow ACOs—perhaps ACOs in different geographic market areas—to form coalitions to apply for waivers. Waivers could be granted on the condition that coalition members agree to randomization of incentive use among participating ACOs. This approach would be more difficult to coordinate and perhaps less attractive to ACOs concerned about being randomized to the control group, but it would allow for consistency among an ACO's assigned beneficiaries.

A conditioned waiver that takes this form would offer some advantages over existing approaches to eliciting information about beneficiary inducements. Under existing regulations, ACOs are required to “define, establish, implement, evaluate, and periodically update processes” to “[p]romote patient engagement.”<sup>212</sup> The shared savings program application requires ACOs to submit narratives describing how the ACO will complete these tasks.<sup>213</sup> Federal regulators may therefore have some access to information about incentives that ACOs plan to use. This information, however, may not be sufficiently detailed to allow for clear evaluation or provided in a format that would allow for straightforward aggregation of data across ACOs. ACOs may be required to undertake evaluations, but the regulations neither specify the nature of the evaluation nor require reporting

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212. 42 C.F.R. § 425.112(b) (2013).

213. See CTRS. FOR MEDICARE & MEDICAID SERVS., DEP'T OF HEALTH & HUMAN SERVS., MEDICARE SHARED SAVINGS PROGRAM APPLICATION 18 (2012), *available at* [https://www.cms.gov/sharedsavingsprogram/Downloads/Medicare\\_Shared\\_Savings\\_Program\\_Application\\_2012.pdf](https://www.cms.gov/sharedsavingsprogram/Downloads/Medicare_Shared_Savings_Program_Application_2012.pdf).



of evaluation results.<sup>214</sup> A conditioned waiver could be used to make more meaningful data available to regulators in forms that could be used to perform broader evaluations. At the same time, conditioned waivers offer some advantages over traditional, formal demonstration projects in that they would allow for broader participation and more flexibility in the arrangements adopted.

Another example of an area in which waivers conditioned on experimentation might be useful involves a different type of incentive: employer incentives for healthy behaviors. A number of employers would like to offer wellness incentives through their health plans, such as rewards for employees who reach a target cholesterol level.<sup>215</sup> Incentives have the potential to promote health, but they also have the potential to discriminate against the unhealthy and make insurance unaffordable.<sup>216</sup> In recognition of both the benefits and risks of wellness incentives, the ACA allows incentives tied to standards based on health-related factors, but limits their use.<sup>217</sup> One such limit is that, in the aggregate, these wellness rewards cannot exceed thirty percent of the total cost of insurance coverage.<sup>218</sup> But the statute also contemplates the possibility of relaxing this limit: it grants the Secretaries of Labor, Health and Human Services, and the Treasury the authority to raise this limit to fifty percent “if the Secretaries determine that such an increase is appropriate.”<sup>219</sup>

How might the Secretaries decide whether the increase is “appropriate”? The Secretaries could solicit comments on the potential costs and benefits of increasing the threshold. Insurers, employers, patient advocates, and researchers in the field could relay their opinions about the actual impact of the current threshold and predictions about the possible impact of a higher threshold. The ACA, however, does not call for a demonstration project in which the higher threshold would actually be tested. If regulators were able (at least temporarily) to condition the availability of the fifty percent

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214. See generally 42 C.F.R. § 425.112 (2013).

215. See Heather Baird, Note, *Health Compromise: Reconciling Wellness Program Financial Incentives with Health Reform*, 97 MINN. L. REV. 1474, 1488–89 (2013).

216. See Kristin M. Madison, Kevin G. Volpp & Scott D. Halpern, *The Law, Policy, and Ethics of Employers' Use of Financial Incentives to Improve Health*, 39 J.L. MED. & ETHICS 450, 451–54 (2011).

217. See Patient Protection and Affordable Care Act § 2705, 42 U.S.C. § 300gg-4(j) (2012).

218. Patient Protection and Affordable Care Act § 2705, 42 U.S.C. § 300gg-4(j)(3)(A) (2012).

219. *Id.*

threshold on participation in a randomized trial (either among one firm's employees or across a coalition of firms), as well as on reporting of the nature of incentives used and the relevant outcome measures, they could generate more reliable information about the impact of higher thresholds. There are both legal and practical impediments to this sort of arrangement,<sup>220</sup> but when the implications of such a significant change in regulation are unclear, the arrangement could provide very useful information while limiting the population exposed to the risks. Ultimately, the Secretaries increased the ceiling to fifty percent for certain programs targeting tobacco use, but referenced other regulations, rather than empirical evidence, as the basis for their decision.<sup>221</sup>

Federal and state governments impose many different types of reporting requirements, and many government programs, including waiver programs, require some sort of reporting as a condition of participation.<sup>222</sup> A waiver explicitly conditioned on experimentation, however, might help build a stronger foundation for generating evidence on the impact of specific policy approaches. The federal government has shown a willingness to condition policies on systematic data collection or experimentation in the past. Under the Medicare program's coverage with evidence development policy, for example, Medicare pays for certain services only for patients participating in a registry or clinical trial involving those services.<sup>223</sup> Treating experimentation as a condition for a waiver might generate useful information in a wider set of policy domains.<sup>224</sup>

Broader implementation of conditioned waivers would involve many challenges. If the conditions for waivers go beyond reporting requirements to include some sort of randomization in exposure to a particular program, policy, or practice, questions of ethics and equity will invariably arise.

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220. See Madison et al., *supra* note 216, at 463–65 (describing legal and practical impediments to research on employer use of incentives).

221. Incentives for Nondiscriminatory Wellness Programs in Group Health Plans, 78 Fed. Reg. 33,157, 33,166–67 (June 3, 2013), *available at* <https://www.federalregister.gov/articles/2013/06/03/2013-12916/incentives-for-nondiscriminatory-wellness-programs-in-group-health-plans>.

222. See discussion of Section 1115 waivers in Part III.A.

223. See Steven D. Pearson, Franklin G. Miller & Ezekiel J. Emanuel, *Medicare's Requirement for Research Participation as a Condition of Coverage: Is It Ethical?*, 296 JAMA 988, 988–89 (2006) (describing coverage with evidence development policy).

224. Several policy analysts have suggested that CMS adopt an “innovation with evidence development” approach to implementing system innovation. Guterman et al., *supra* note 125, at 1190–91.

Some patients may be upset if they do not qualify for incentives, while others do. Critiques of Medicare's coverage with evidence development policy have raised questions both about fairness generally and about the need to treat aspects of the policy as research—a classification that would bring with it a mandate for informed consent as well as a host of other requirements.<sup>225</sup> Regulatory and policy experimentation, like medical experimentation, raises many ethical issues.<sup>226</sup> The fact that under the conditioned waiver approach, the experiment would be conducted by the regulated entity, rather than directly by the regulator, would not eliminate those concerns and may even exacerbate them.

Conditioned waivers could also be burdensome, particularly relative to a policy such as the blanket waiver for ACO beneficiary inducement, which requires neither an application nor waiver-specific reporting. Waivers that allow for a lot of flexibility and involve minimal oversight reduce burdens on both regulators and regulated entities. But the more attention regulators devote to crafting reporting and other requirements, whether through blanket waivers or case-by-case consideration of waiver applications, the higher the likely quality of the resulting evaluation. Ultimately, the benefits of more and better information must be weighed against the risks of discouraging waiver requests and chilling innovation. Conditioned waivers will not always be an attractive regulatory approach, but in areas where the need for additional information is particularly acute, they may be worthwhile.

## V. CONCLUSION

The Patient Protection and Affordable Care Act facilitates experimentation among both states and providers by preserving flexibility, supporting demonstration programs, and altering incentives. At the same time, however, the federal government could do more to promote innovation, systematic evaluation, and widespread dissemination of findings. By tying funding to policy outcomes, making use of regulatory variation, and conditioning waivers on systematic evaluation, the federal government could improve the performance of the nation as a laboratory.

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225. See Pearson et al., *supra* note 223, at 989–90.

226. See Abramowicz et al., *supra* note 50, at 963–74 (discussing ethical and equality issues implicated by randomizing law). See generally ETHICAL AND LEGAL ISSUES OF SOCIAL EXPERIMENTATION (Alice M. Rivlin & P. Michael Timpane eds., 1975) (exploring ethical issues in social experimentation).

This Article used health-related examples to illustrate each of these policy approaches. Information failures and other flaws that plague health care markets, along with the significant federal role in financing health care, make the health area especially well-suited for federal initiatives designed to enhance experimentation. But these same approaches could be applied to other areas of policy, too. In enacting regulations, regulators often must decide on a regulatory approach with limited information about the potential impact of their choices. Scholars have called for retrospective evaluation of regulations,<sup>227</sup> and an executive order states as a general principle that the regulatory system “must measure . . . the actual results of regulatory requirements.”<sup>228</sup> Regulating with variation could help support measurement efforts, regardless of the particular policy area affected.<sup>229</sup>

There would undoubtedly be many policy, political, and practical challenges involved in building a better federal laboratory, whether through the approaches suggested in this Article or others. But given the potential benefits of health system experimentation, it is important to begin to confront these challenges.

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227. See, e.g., Cary Coglianese, *Federal Regulations: Let's Review the Rules*, L.A. TIMES (Apr. 29, 2011), <http://articles.latimes.com/2011/apr/29/opinion/la-oe-coglianese-regulations-20110429>.

228. Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 18, 2011).

229. Cary Coglianese notes that “[t]o do retrospective evaluation well, agencies must engage in advance planning: making early decisions about how data will be defined and collected over time and what relevant control groups might be used for making comparisons.” Coglianese, *supra* note 227. Regulatory variation could be part of this sort of advance planning process.

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